

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: In the nature of a substitute.

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

**S. 1895**

To lower health care costs.

Referred to the Committee on \_\_\_\_\_ and  
ordered to be printed

Ordered to lie on the table and to be printed

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

Viz:

1 Strike all after the enacting clause and insert the fol-  
2 lowing:

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**

## 2

- 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.

## 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  
 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                   freestanding emergency room” after  
 14                   “emergency department”; and

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

18                   (2) in paragraph (2)(B)—

1 (A) in clause (i)—

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

4 (ii) by inserting “or freestanding  
5 emergency room” after “emergency depart-  
6 ment”; and

7 (B) in clause (ii), by inserting “or free-  
8 standing emergency 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) OUT-OF-NETWORK ANCILLARY SERVICES.—

14 “(1) COVERAGE OF SERVICES.—Subject to sub-  
15 section (h), in the case of an enrollee in a group  
16 health plan or group or individual health insurance  
17 coverage who receives out-of-network ancillary serv-  
18 ices at an in-network facility, including any referrals  
19 for diagnostic services, and such services would be  
20 covered under such plan or coverage if provided in-  
21 network—

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

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

4 “(B) amounts paid toward such cost-shar-  
5 ing shall be counted towards the in-network de-  
6 ductible and in-network out-of-pocket maximum  
7 amount, as applicable, under the plan or cov-  
8 erage for the plan year.

9 “(2) NOTICE BEFORE PROVIDING NON-EMER-  
10 GENCY SERVICES.—Subject to subsection (h), in the  
11 case of an enrollee in a group health plan or group  
12 or individual health insurance coverage who receives  
13 out-of-network, non-emergency services that are not  
14 ancillary services, from an out-of-network provider  
15 at an in-network facility, and such services would be  
16 covered under such plan or coverage if provided in-  
17 network, the cost-sharing requirement (expressed as  
18 a copayment amount, coinsurance rate, or deduct-  
19 ible) with respect to such services shall be the same  
20 requirement that would apply if such services were  
21 provided by an in-network practitioner, and any co-  
22 insurance or deductible shall be based on in-network  
23 rates, unless, as soon as practicable, and in no case  
24 later than 48 hours prior to providing non-emer-  
25 gency services that are not ancillary services—

1           “(A) the in-network facility provides to the  
2 enrollee who is scheduled to receive such serv-  
3 ices notice that—

4                   “(i) is provided in paper or electronic  
5 form (and including electronic notification  
6 whenever practicable);

7                   “(ii) states that such service will be  
8 provided out-of-network;

9                   “(iii) includes the estimated amount  
10 that such practitioner or facility may  
11 charge the enrollee for such services; and

12                   “(iv) provides the option to affirma-  
13 tively consent to receiving such services  
14 from such practitioner or facility;

15           “(B) such enrollee signs such notice con-  
16 senting to receive such services from an out-of-  
17 network provider at an in-network facility, and  
18 acknowledging that the out-of-network services  
19 may be covered at an out-of-network cost-shar-  
20 ing amount, requiring higher cost-sharing obli-  
21 gations of the enrollee than if the service were  
22 provided by an in-network practitioner or facil-  
23 ity; and

24           “(C) such facility maintains documentation  
25 of the enrollee’s signature or confirmation of re-

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

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

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

9            “(1) PROTECTION FOR ENROLLEES ADMITTED  
10           TO THE HOSPITAL FOR EMERGENCY SERVICES PRIOR  
11           TO STABILIZATION.—In the case of an enrollee in a  
12           group health plan or group or individual health in-  
13           surance coverage who receives emergency services, or  
14           maternal care for a woman in labor, in the emer-  
15           gency department of an out-of-network facility and  
16           has not been stabilized (within the meaning of sub-  
17           section (b)(2)(C)), if the patient is subsequently ad-  
18           mitted to the out-of-network facility for care, the  
19           cost-sharing requirement (expressed as a copayment  
20           amount, coinsurance rate, or deductible) with re-  
21           spect to any out-of-network services provided to the  
22           enrollee prior to being stable and in a condition to  
23           receive information under (2), is the same require-  
24           ment that would apply as under subsection  
25           (b)(2)(C)(ii)(II).

1 “(2) NOTICE AND CONSENT.—

2 “(A) IN GENERAL.—Subject to subsection  
3 (h), in the case of an enrollee in a group health  
4 plan or group or individual health insurance  
5 coverage who receives emergency services, or  
6 maternal care for a woman in labor, in the  
7 emergency department of an out-of-network fa-  
8 cility and has been stabilized (within the mean-  
9 ing of subsection (b)(2)(C)), if the patient is  
10 subsequently admitted to the out-of-network fa-  
11 cility for care, the cost-sharing requirement (ex-  
12 pressed as a copayment amount, coinsurance  
13 rate, or deductible) with respect to any out-of-  
14 network services is the same requirement that  
15 would apply if such services were provided by  
16 an in-network provider, unless the enrollee, once  
17 stable and in a condition to receive such infor-  
18 mation, including having sufficient mental ca-  
19 pacity—

20 “(i) has been provided by the facility,  
21 prior to the provision of any post-stabiliza-  
22 tion, out-of-network service at such facility,  
23 with—

24 “(I) paper or electronic notifica-  
25 tion that the practitioner or facility is



1 an out-of-network health care provider  
2 and the out-of-network rate of the  
3 provider, as applicable, and the option  
4 to affirmatively consent to receiving  
5 services from such practitioner or fa-  
6 cility; and

7 “(II) the estimated amount that  
8 such provider may charge the partici-  
9 pant, beneficiary, or enrollee for such  
10 services involved;

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

15 “(I) paper or electronic notifica-  
16 tion (and including electronic notifica-  
17 tion whenever practicable) that the  
18 practitioner or facility is an out-of-  
19 network health care provider, and the  
20 option to affirmatively consent to re-  
21 ceiving services from such practitioner  
22 or facility;

23 “(II) a list of in-network practi-  
24 tioners or facilities in the relevant ge-  
25 ographic area that could provide the

1 same services, and an option for a re-  
2 ferral to such providers; and

3 “(III) information about whether  
4 prior authorization or other care man-  
5 agement limitations may be required  
6 in advance of receiving in-network  
7 services at the facility;

8 “(iii) has acknowledged, in writing,  
9 that the out-of-network services provided  
10 after the individual has been stabilized  
11 may not be covered or may be covered at  
12 an out-of-network cost-sharing amount, re-  
13 quiring higher cost-sharing obligations of  
14 the enrollee than if the service were pro-  
15 vided at an in-network facility.

16 “(B) REQUIREMENTS OF NOTICE.—The  
17 notice under subparagraph (A) shall be in a for-  
18 mat determined by the Secretary to give a rea-  
19 sonable layperson clear comprehension of the  
20 terms of the agreement, including all possible  
21 financial responsibilities, including the require-  
22 ments that the notice—

23 “(i) does not exceed one page in  
24 length;

1 “(ii) is readily identifiable for its pur-  
2 pose and as a contract of consent;

3 “(iii) clearly states that consent to po-  
4 tential out-of-network charges is optional  
5 and that the enrollee has the choice to  
6 transfer to an in-network facility;

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

11 “(v) be available in the 15 most com-  
12 mon languages in the facility’s geographic  
13 area, with the facility making a good faith  
14 effort to provide oral notice in the enroll-  
15 ee’s primary language if it is not one of  
16 such 15 languages.

17 “(C) MAINTENANCE OF RECORDS.—A fa-  
18 cility shall maintain documentation of notice  
19 given to an enrollee pursuant to this subsection  
20 and the enrollee’s confirmation of receipt of  
21 such information in the enrollee’s patient record  
22 for 2 years after the date of services.

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

1 to carry out this subsection, which shall include clar-  
2 ification on how to determine whether an individual  
3 is stabilized and the timing of the notice required  
4 under this paragraph.

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

7 “(1) IN GENERAL.—A facility or practitioner  
8 furnishing—

9 “(A) emergency services, as defined in sub-  
10 section (b)(2), regardless of the State in which  
11 the patient resides;

12 “(B) out-of-network services at an in-net-  
13 work facility described in subsection (e)(1);

14 “(C) out-of-network services at an in-net-  
15 work facility described in subsection (e)(2),  
16 where the notice and consent for receiving such  
17 services out-of-network did not meet the re-  
18 quirement of such subsection;

19 “(D) services furnished by an out-of-net-  
20 work provider after an enrollee has been admit-  
21 ted to the hospital for emergency services but  
22 prior to stabilization, as described in subsection  
23 (f)(1); or

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

1 meaning of subsection (b)(2)(C)), where the no-  
2 tice and option for receiving care at an alter-  
3 nate facility required under subsection (f)(2)  
4 have not been provided to the enrollee and the  
5 enrollee did not give consent under subsection  
6 (f)(3),  
7 may not bill an enrollee in a group health plan or  
8 group or individual health insurance coverage for  
9 amounts beyond the cost-sharing amount that would  
10 apply under subsection (b)(1)(C)(ii)(II), (e)(1),  
11 (e)(2), or (f), as applicable.

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

1       “(h) MAINTAINING STATE SURPRISE BILLING PRO-  
2 TECTIONS.—

3           “(1) IN GENERAL.—Nothing in this section  
4 shall prevent a State from establishing or continuing  
5 in effect, with respect to health insurance issuers,  
6 facilities, or practitioners, an alternate method under  
7 State law for determining the appropriate compensa-  
8 tion for services described in subsection (b), (e), or  
9 (f).

10           “(2) ADDITIONAL APPLICATION.—In the case of  
11 group health plans or group or individual health in-  
12 surance coverage offered in a State that has not es-  
13 tablished an alternate method described in para-  
14 graph (1), such as arbitration or a benchmark, or  
15 for services described in subsection (b), (e), or (f)  
16 that are not covered by such State’s alternate meth-  
17 od described in paragraph (1), the provisions of this  
18 section shall apply.

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

23       “(i) DEFINITIONS.—In this section:

24           “(1) IN-NETWORK.—The term ‘in-network’,  
25 with respect to a group health plan or health insur-

1           ance coverage means a provider that has a contrac-  
2           tual relationship with the plan.

3           “(2) ENROLLEE.—The term ‘enrollee’, with re-  
4           spect to health insurance coverage or a group health  
5           plan, includes a participant, dependent, or bene-  
6           ficiary.

7           “(3) ANCILLARY SERVICES.—The term ‘ancil-  
8           lary services’ means non-emergency care that is—

9                   “(A) provided by anesthesiologists, pa-  
10                  thologists, emergency medicine providers,  
11                  intensivists, radiologists, neonatologists,  
12                  hospitalists, and assistant surgeons, whether  
13                  the care is provided by a physician or non-phy-  
14                  sician practitioner;

15                  “(B) a diagnostic service (including radi-  
16                  ology and lab services); or

17                  “(C) provided by such other specialty prac-  
18                  titioner not typically selected by the patients re-  
19                  ceiving the care, which the Secretary may add  
20                  periodically to such definition through rule-  
21                  making.”.

22           (b) ENFORCEMENT OF BALANCE BILLING PROHIBI-  
23           TIONS.—Part C of title XXVII of the Public Health Serv-  
24           ice Act (42 U.S.C. 300gg–91 et seq.) is amended by add-  
25           ing at the end the following:

1 **“SEC. 2795. ENFORCEMENT OF BALANCE BILLING PROHIBI-**  
2 **TIONS.**

3 “(a) IN GENERAL.—Subject to subsection (b), a facil-  
4 ity or practitioner that violates a requirement under sec-  
5 tion 2719A(g)(1) or fails to provide notice or obtain con-  
6 sent as required under subsection (e)(2) or (f)(2) shall be  
7 subject to a civil monetary penalty of not more than  
8 \$10,000 for each act constituting such violation.

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

16 “(c) SAFE HARBOR.—

17 “(1) IN GENERAL.—The Secretary shall waive  
18 the penalties described under subsection (a) with re-  
19 spect to a facility or, practitioner who does not  
20 knowingly violate, and should not have reasonably  
21 known it violated, section 2719A(g)(1) with respect  
22 to an enrollee, if such facility or practitioner, within  
23 30 days of the violation, withdraws the bill that was  
24 in violation of section 2719A(g)(1), and, as applica-  
25 ble, reimburses the group health plan, health insur-  
26 ance issuer, or enrollee, in an amount equal to the



1 difference between the amount billed and the  
2 amount allowed to be billed under section  
3 2719A(g)(1), plus interest, at an interest rate deter-  
4 mined by the Secretary.

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

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

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

17 “(5) APPLICATION OF ADDITIONAL PROVI-  
18 SIONS.—Subsections (b) through (h) of section  
19 2719A of the Public Health Service Act (42 U.S.C.  
20 300gg–19a) shall apply to grandfathered health  
21 plans for plan years beginning with the second plan  
22 year that begins after the date of enactment of the  
23 Lower Health Care Costs Act.”.

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

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

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

9 **SEC. 103. BENCHMARK FOR PAYMENT.**

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

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

15 “(a) ESTABLISHMENT OF BENCHMARK.—A group  
16 health plan or health insurance issuer offering group or  
17 individual health insurance coverage shall pay providers,  
18 including facilities and practitioners, furnishing services  
19 for which such facilities and practitioners are prohibited  
20 under section 2719A(g) from billing enrollees for amounts  
21 beyond the cost-sharing amount that would apply under  
22 subsection (b)(1)(C)(ii)(II), (e), or (f) of section  
23 2719A, the median in-network rate for such services pro-  
24 vided to enrollees, using a methodology determined under  
25 subsection (b) for the same or similar services offered by

1 the group health plan or health insurance issuer in that  
2 geographic region. Such payment shall be made in a timely  
3 fashion in order to ensure compliance with sections 399V–  
4 7 and 2729D.

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 contracted 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.—

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

1           ferentiating by business line, the information  
2           the plan or issuer shall share with the out-of-  
3           network provider involved when making such a  
4           determination, and the geographic regions ap-  
5           plied for purposes of this subsection. Such rule-  
6           making shall take into account payments that  
7           are made by health insurance issuers that are  
8           not on a fee-for-service basis.

9           “(B) GEOGRAPHIC REGIONS.—In estab-  
10          lishing geographic regions under subparagraph  
11          (A), the Secretary shall consider adequate ac-  
12          cess to services in rural areas and health pro-  
13          fessional shortage areas, as defined in section  
14          332. The Secretary shall consult with the Na-  
15          tional Association of Insurance Commissioners  
16          in establishing the geographic regions. The Sec-  
17          retary shall update the geographic regions peri-  
18          odically, as appropriate, taking into account the  
19          findings of the report under section 106 of the  
20          Lower Health Care Costs Act.

21          “(3) CERTAIN INSURERS.—If a group health  
22          plan or health insurance issuer offering group or in-  
23          dividual health insurance coverage does not have  
24          sufficient information to calculate a median in-net-  
25          work rate for this service or provider type, or

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

17 “(4) RULE OF CONSTRUCTION.—Nothing in  
18 this subsection shall prevent a group health plan or  
19 health insurance issuer from establishing separate  
20 calculations of a median in-network rate under para-  
21 graph (1) for services delivered in nonhospital facili-  
22 ties, including freestanding emergency rooms.

23 “(c) FACILITY.—For purposes of this section, the  
24 term ‘health care facility’ or ‘facility’ includes hospitals,  
25 hospital outpatient departments, critical access hospitals,

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

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

11 **SEC. 104. EFFECTIVE DATE.**

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

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

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

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

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

1           “(1) the cost-sharing requirement (expressed as  
2           a copayment amount, coinsurance rate, or deduct-  
3           ible) with respect to such services shall be the same  
4           requirement that would apply if such services were  
5           provided by an in-network practitioner, and any co-  
6           insurance or deductible shall be based on in-network  
7           rates; and

8           “(2) such cost-sharing amounts shall be count-  
9           ed towards the in-network deductible and in-network  
10          out-of-pocket maximum amount under the plan or  
11          coverage for the plan year.

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

16          “(c) MEDIAN IN-NETWORK RATE.—

17                 “(1) IN GENERAL.—For purposes of this sec-  
18                 tion, the term ‘median in-network rate’ means, with  
19                 respect to air ambulance services covered by a group  
20                 health plan or group or individual health insurance  
21                 coverage, the median contracted rate under the ap-  
22                 plicable plan or coverage recognized under the plan  
23                 or coverage as the total maximum payment for the  
24                 service, minus the in-network cost-sharing for such  
25                 service under the plan or coverage, for the same or

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

4 “(2) RULEMAKING.—

5 “(A) IN GENERAL.—Not later than 6  
6 months after the date of enactment of the  
7 Lower Health Care Costs Act, the Secretary  
8 shall, through rulemaking, determine the meth-  
9 odology a group health plan or health insurance  
10 issuer is required to use to determine the me-  
11 dian in-network rate described in paragraph  
12 (1), the information the plan or issuer shall  
13 share with the out-of-network provider involved  
14 when making such a determination, and the ge-  
15 ographic regions applied for purposes of this  
16 subsection. Such rulemaking shall take into ac-  
17 count payments that are made by issuers that  
18 are not on a fee-for-service basis.

19 “(B) GEOGRAPHIC REGIONS.—In estab-  
20 lishing geographic regions as described in sub-  
21 paragraph (A), the Secretary shall consider  
22 adequate access to services in rural areas. The  
23 Secretary shall consult with the National Asso-  
24 ciation of Insurance Commissioners in estab-  
25 lishing the geographic regions. The Secretary



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

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

1           “(4) CLARIFICATION.—For purposes of this  
2 subsection, the Secretary may define geographic re-  
3 gions that are different from the geographic regions  
4 identified for purposes of section 2729A(b) to ensure  
5 that an adequate number of air ambulance services  
6 are in-network in each geographic region so that a  
7 median in-network rate for air ambulance services  
8 may be 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  
13 under subsection (a).

14           “(e) ENFORCEMENT.—

15           “(1) IN GENERAL.—Subject to paragraph (2),  
16 an air ambulance service provider that violates sub-  
17 section (d) shall be subject to a civil monetary pen-  
18 alty of not more than \$10,000 for each act consti-  
19 tuting 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 enact-  
18 ment of this Act.

19 **SEC. 106. REPORT.**

20 Not later than 1 year after the effective date de-  
21 scribed in section 104, and annually for the following 4  
22 years, the Secretary of Health and Human Services, in  
23 consultation with the Federal Trade Commission and the  
24 Attorney General, 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  
7 by sections 101, 102, 103, and 105 on overall  
8 health care costs;

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

14 (D) recommendations, made in consulta-  
15 tion with the Secretary of Labor and the Sec-  
16 retary of the Treasury, for effective enforce-  
17 ment of 2729A of the Public Health Service  
18 Act, as added by section 103, including poten-  
19 tial challenges to addressing anti-competitive  
20 consolidation by health care facilities, providers,  
21 group health plans, or health insurance issuers;  
22 and

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

1 portation, the Committee on Finance, and the Com-  
2 mittee on the Judiciary of the Senate and the Com-  
3 mittee on Education and Labor, the Committee on  
4 Energy and Commerce, the Committee on Ways and  
5 Means, and the Committee on the Judiciary of the  
6 House of Representatives.

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

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

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

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

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

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

1                   “(B) PREVIOUSLY APPROVED OR LI-  
2                   CENSED BIOLOGICAL PRODUCTS.—

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

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

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

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

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

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

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

14                          “(ii) any patent, or any claim with re-  
15                          spect to a patent, included on the list pur-  
16                          suant to this paragraph, that the Patent  
17                          Trial and Appeal Board of the United  
18                          States Patent and Trademark Office deter-  
19                          mines in a written decision to cancel as  
20                          unpatentable, within 30 days of such deci-  
21                          sion.

22           “(2) PUBLICATION OF INFORMATION.—

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

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

3 “(i) the official and proprietary name  
4 of each biological product licensed, or  
5 deemed to be licensed, under subsection (a)  
6 or (k);

7 “(ii) with respect to each biological  
8 product described in clause (i), each patent  
9 submitted in accordance with paragraph  
10 (1);

11 “(iii) the date of licensure and appli-  
12 cation number for each such biological  
13 product;

14 “(iv) the marketing status, dosage  
15 form, route of administration, strength,  
16 and, if applicable, reference product, for  
17 each such biological product;

18 “(v) the licensure status for each such  
19 biological product, including whether the li-  
20 cense at the time of listing is approved,  
21 withdrawn, or revoked;

22 “(vi) with respect to each such bio-  
23 logical product, any period of exclusivity  
24 under paragraph (6), (7)(A), or (7)(B) of  
25 subsection (k) of this section or section



1 527 of the Federal Food, Drug, and Cos-  
2 metic Act, and any extension of such pe-  
3 riod in accordance with subsection (m) of  
4 this section, for which the Secretary has  
5 determined such biological product to be  
6 eligible, and the date on which such exclu-  
7 sivity expires;

8 “(vii) any determination of biosimi-  
9 larity or interchangeability for each such  
10 biological product; and

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

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

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

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

1                   “(ii) any updates to information pre-  
2                   viously published in accordance with sub-  
3                   paragraph (A).

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

22                  “(3) PATENTS REQUIRED TO BE DISCLOSED.—  
23                  In this section, a ‘patent required to be disclosed’ is  
24                  any patent for which the holder of a biological prod-  
25                  uct license approved under subsection (a) or (k), or

1 a biological product application approved under sec-  
2 tion 505 of the Federal Food, Drug, and Cosmetic  
3 Act and deemed to be a license for a biological prod-  
4 uct under this section on March 23, 2020, believes  
5 a claim of patent infringement could reasonably be  
6 asserted by the holder, or by a patent owner that  
7 has granted an exclusive license to the holder with  
8 respect to the biological product that is the subject  
9 of such license, if a person not licensed by the owner  
10 engaged in the making, using, offering to sell, sell-  
11 ing, or importing into the United States of the bio-  
12 logical product that is the subject of such license.”.

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

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

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

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

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

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

13 (e) RULE OF CONSTRUCTION.—Nothing in this Act,  
14 including an amendment made by this Act, shall be con-  
15 strued to require or allow the Secretary of Health and  
16 Human Services to delay the licensing of a biological prod-  
17 uct under section 351 of the Public Health Service Act  
18 (42 U.S.C. 262).

19 **SEC. 202. ORANGE BOOK MODERNIZATION.**

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

22 (1) IN GENERAL.—Paragraph (1) of section  
23 505(b) of the Federal Food, Drug, and Cosmetic Act  
24 (21 U.S.C. 355(b)) is amended to read as follows:

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

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

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

10           “(iii) a full statement of the composition of  
11 such drug;

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

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

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

20           “(vii) any assessments required under section  
21 505B; and

22           “(viii) the patent number and expiration date,  
23 of each patent for which a claim of patent infringe-  
24 ment could reasonably be asserted if a person not li-

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

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

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

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

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

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

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

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

22 (2) by inserting after “the patent number and  
23 the expiration date of any patent which” the fol-  
24 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)(1)(A)(viii)”.

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

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

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

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

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

25                 “(IV) section 505A;



1 “(V) section 505E;

2 “(VI) section 527(a); or

3 “(VII) subsection (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 for such drug,  
14 and where the Under Secretary of Commerce for In-  
15 tellectual Property and Director of the United States  
16 Patent and Trademark Office have cancelled any  
17 claim of the patent pursuant to a decision by the  
18 Patent Trial and Appeal Board in an inter partes  
19 review conducted under chapter 31 of title 35,  
20 United States Code, or a post-grant review con-  
21 ducted under chapter 32 of that title, and from  
22 which no appeal has been taken, or can be taken,  
23 the holder of the applicable approved application  
24 shall notify the Secretary, in writing, within 14 days  
25 of such cancellation, and, if the patent has been

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

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

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

1 subject of such certification was included in such list  
2 with respect to the listed drug.”.

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

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

6 (1) in paragraph (1)—

7 (A) in subparagraph (A)(i), by inserting “,  
8 10.31,” after “10.30”;

9 (B) in subparagraph (E)—

10 (i) by striking “application and” and  
11 inserting “application or”;

12 (ii) by striking “If the Secretary” and  
13 inserting the following:

14 “(i) IN GENERAL.—If the Secretary”;  
15 and

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

18 “(ii) PRIMARY PURPOSE OF DELAY-  
19 ING.—

20 “(I) IN GENERAL.—In deter-  
21 mining whether a petition was sub-  
22 mitted with the primary purpose of  
23 delaying an application, the Secretary  
24 may consider the following factors:

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

8                   “(bb) Whether the petitioner  
9 has submitted multiple or serial  
10 petitions or supplements to peti-  
11 tions raising issues that reason-  
12 ably could have been known to  
13 the petitioner at the time of sub-  
14 mission of the earlier petition or  
15 petitions.

16                   “(cc) Whether the petition  
17 was submitted close in time to a  
18 known, first date upon which an  
19 application under subsection  
20 (b)(2) or (j) of this section or  
21 section 351(k) of the Public  
22 Health Service Act could be ap-  
23 proved.

24                   “(dd) Whether the petition  
25 was submitted without relevant

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

4 “(ee) Whether the petition  
5 raises the same or substantially  
6 similar issues as a prior petition  
7 to which the Secretary has re-  
8 sponded substantively already, in-  
9 cluding if the subsequent submis-  
10 sion follows such response from  
11 the Secretary closely in time.

12 “(ff) Whether the petition  
13 requests changing the applicable  
14 standards that other applicants  
15 are required to meet, including  
16 requesting testing, data, or label-  
17 ing standards that are more on-  
18 erous or rigorous than the stand-  
19 ards the Secretary has deter-  
20 mined to be applicable to the list-  
21 ed drug, reference product, or pe-  
22 titioner’s version of the same  
23 drug.

24 “(gg) The petitioner’s record  
25 of submitting petitions to the

1 Food and Drug Administration  
2 that have been determined by the  
3 Secretary to have been submitted  
4 with the primary purpose of  
5 delay.

6 “(hh) Other relevant and  
7 appropriate factors, which the  
8 Secretary shall describe in guid-  
9 ance.

10 “(II) GUIDANCE.—The Secretary  
11 may issue or update guidance, as ap-  
12 propriate, to describe factors the Sec-  
13 retary considers in accordance with  
14 subclause (II).”;

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

16 “(iii) REFERRAL TO THE FEDERAL  
17 TRADE COMMISSION.—The Secretary shall  
18 establish procedures for referring to the  
19 Federal Trade Commission any petition or  
20 supplement to a petition that the Secretary  
21 determines was submitted with the primary  
22 purpose of delaying approval of an applica-  
23 tion. Such procedures shall include notifi-  
24 cation to the petitioner by the Secretary.”;

25 (D) by striking subparagraph (F);

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

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

7 (2) in paragraph (2)—

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

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

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

1           “(B) TIMELY SUBMISSION OF CITIZEN PE-  
2           TITION.—A petition and any supplement to a  
3           petition shall be submitted within 60 days after  
4           the person knew, or reasonably should have  
5           known, the information that forms the basis of  
6           the request made in the petition or supple-  
7           ment.”;

8           (C) in subparagraph (C), as so redesign-  
9           nated—

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

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

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

17           “(ii) on or after the date that is 151  
18           days after the date of submission of the  
19           petition, the Secretary approves or has ap-  
20           proved the application that is the subject  
21           of the petition without having made such a  
22           final decision.”;

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



1                   “(D) DISMISSAL OF CERTAIN CIVIL AC-  
2                   TIONS.—

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

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

1                   “(iii) FINAL RESPONSE.—If a civil ac-  
2                   tion is filed against the Secretary with re-  
3                   spect to any issue raised in a petition time-  
4                   ly filed under paragraph (1) in which the  
5                   petitioner requests that the Secretary take  
6                   any form of action that could, if taken, set  
7                   aside, delay, rescind, withdraw, or prevent  
8                   submission, review, or approval of an appli-  
9                   cation submitted under subsection (b)(2)  
10                  or (j) of this section or section 351(k) of  
11                  the Public Health Service Act before the  
12                  Secretary has taken final agency action on  
13                  the petition within the meaning of sub-  
14                  paragraph (C), the court shall dismiss  
15                  without prejudice the action for failure to  
16                  exhaust administrative remedies.”; and

17                  (E) in clause (iii) of subparagraph (E), as  
18                  so redesignated, by striking “as defined under  
19                  subparagraph (2)(A)” and inserting “within the  
20                  meaning of subparagraph (C)”;

21                  (3) in paragraph (4)—

22                  (A) by striking “EXCEPTIONS” and all that  
23                  follows through “This subsection does” and in-  
24                  serting “EXCEPTIONS.—This subsection does”;

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

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

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

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

8 “(D) DEEMED LICENSES.—

9 “(i) NO ADDITIONAL EXCLUSIVITY  
10 THROUGH DEEMING.—An approved appli-  
11 cation that is deemed to be a license for a  
12 biological product under this section pursu-  
13 ant to section 7002(e)(4) of the Biologics  
14 Price Competition and Innovation Act of  
15 2009 shall not be treated as having been  
16 first licensed under subsection (a) for pur-  
17 poses of subparagraphs (A) and (B).

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



1                   “(AA) An application for the  
2 drug submitted by an applicant other  
3 than a first applicant has received  
4 tentative approval and could receive  
5 approval, if no first applicant were eli-  
6 gible for 180-day exclusivity under  
7 this clause, and such applicant has  
8 not entered into an agreement that  
9 would prevent commercial marketing  
10 upon approval and has submitted a  
11 notification to the Secretary docu-  
12 menting that it has not entered into  
13 an agreement that would prevent com-  
14 mercial marketing.

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

23                   “(CC) Approval of an application  
24 for the drug submitted by at least one

1 first applicant would not be precluded  
2 under clause (iii).”.

3 (b) INFORMATION.—Not later than 60 days of the  
4 date of enactment of this Act, the Secretary of Health and  
5 Human Services (referred to in this subsection as the  
6 “Secretary”) shall publish, as appropriate and available,  
7 information sufficient to allow applicants to assess wheth-  
8 er the conditions described in subitems (AA) through (CC)  
9 of section 505(j)(5)(B)(iv)(I)(bb) of the Federal Food,  
10 Drug, and Cosmetic Act (as amended by subsection (a))  
11 have been or will be satisfied for all applications where  
12 the exclusivity period under (iv)(I) of section 505(j)(5)(B)  
13 of the Federal Food, Drug, and Cosmetic Act (as so  
14 amended) has not expired, and shall provide updates to  
15 reflect the most recent information available to the Sec-  
16 retary.

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

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

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

22 “(a) INTERNET WEBSITE.—

23 “(1) IN GENERAL.—The Secretary may main-  
24 tain and operate an internet website to provide edu-  
25 cational materials for health care providers, patients,

1 and caregivers, regarding the meaning of the terms,  
2 and the standards for review and licensing of, bio-  
3 logical products, including biosimilar biological prod-  
4 ucts and interchangeable biosimilar biological prod-  
5 ucts.

6 “(2) CONTENT.—Educational materials pro-  
7 vided under paragraph (1) may include—

8 “(A) explanations of key statutory and  
9 regulatory terms, including ‘biosimilar’ and  
10 ‘interchangeable’, and clarification regarding  
11 the use of interchangeable biosimilar biological  
12 products;

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

21 “(C) an explanation of the process for re-  
22 porting adverse events for biological products,  
23 including biosimilar biological products and  
24 interchangeable biosimilar biological products;  
25 and

1           “(D) an explanation of the relationship be-  
2           tween biosimilar biological products and inter-  
3           changeable biosimilar biological products li-  
4           censed under section 351(k) and reference  
5           products (as defined in section 351(i)), includ-  
6           ing the standards for review and licensing of  
7           each such type of biological product.

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

10           “(A) in formats such as webinars, con-  
11           tinuing medical education modules, videos, fact  
12           sheets, infographics, stakeholder toolkits, or  
13           other formats as appropriate and applicable;  
14           and

15           “(B) tailored for the unique needs of  
16           health care providers, patients, caregivers, and  
17           other audiences, as the Secretary determines  
18           appropriate.

19           “(4) OTHER INFORMATION.—In addition to the  
20           information described in paragraph (2), the Sec-  
21           retary shall continue to publish the following infor-  
22           mation:

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



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

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

8                   “(b) CONTINUING EDUCATION.—The Secretary shall  
9                   advance education and awareness among health care pro-  
10                  viders regarding biological products, including biosimilar  
11                  biological products and interchangeable biosimilar biological  
12                  products, as appropriate, including by developing or  
13                  improving continuing medical education programs that ad-  
14                  vance the education of such providers on the prescribing  
15                  of, and relevant clinical considerations with respect to, bio-  
16                  logical products, including biosimilar biological products  
17                  and interchangeable biosimilar biological products.”.

18   **SEC. 207. BIOLOGICAL PRODUCT INNOVATION.**

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

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

23                   “(1) a product”;

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

25                   and

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

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

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

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

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

13 (A) in subsection (c)(3)(E), by striking  
14 “active ingredient (including any ester or salt of  
15 the active ingredient)” each place it appears  
16 and inserting “active moiety (as defined by the  
17 Secretary in section 314.3 of title 21, Code of  
18 Federal Regulations (or any successor regula-  
19 tions))”;

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

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

3 (C) in subsection (l)(2)(A)—

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

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

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

14 “(II) for a biological product, no ac-  
15 tive ingredient of which has been approved  
16 in any other application under section 351  
17 of the Public Health Service Act; and”;  
18 and

19 (ii) in clause (ii), by inserting “or bio-  
20 logical product” before the period;

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

23 “(s) REFERRAL TO ADVISORY COMMITTEE.—The  
24 Secretary shall—

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

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

11                   “(B) a biological product, no active ingre-  
12                   dient of which has been approved in any other  
13                   application under section 351 of the Public  
14                   Health Service Act; or

15                  “(2) if the Secretary does not refer a drug or  
16                  biological product described in paragraph (1) to a  
17                  Food and Drug Administration advisory committee  
18                  prior to such approval, provide in the action letter  
19                  on the application for the drug or biological product  
20                  a summary of the reasons why the Secretary did not  
21                  refer the drug or biological product to an advisory  
22                  committee prior to approval.”; and

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

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

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

9 (2) in section 512(c)(2)(F) (21 U.S.C.  
10 360b(c)(2)(F)), by striking “active ingredient (in-  
11 cluding any ester or salt of the active ingredient)”  
12 each place it appears and inserting “active moiety  
13 (as defined by the Secretary in section 314.3 of title  
14 21, Code of Federal Regulations (or any successor  
15 regulations))”;

16 (3) in section 524(a)(4) (21 U.S.C.  
17 360n(a)(4)), by amending subparagraph (C) to read  
18 as follows:

19 “(C) is for—

20 “(i) a human drug, no active moiety  
21 (as defined by the Secretary in section  
22 314.3 of title 21, Code of Federal Regula-  
23 tions (or any successor regulations)) of  
24 which has been approved in any other ap-  
25 plication under section 505(b)(1); or

1                   “(ii) a biological product, no active in-  
2                   gredient of which has been approved in any  
3                   other application under section 351 of the  
4                   Public Health Service Act.”;

5                   (4) in section 529(a)(4) (21 U.S.C. 21 U.S.C.  
6                   360ff(a)(4)), by striking subparagraphs (A) and (B)  
7                   and inserting the following:

8                   “(A) is for a drug or biological product  
9                   that is for the prevention or treatment of a rare  
10                  pediatric disease;

11                  “(B)(i) is for such a drug—

12                   “(I) that contains no active moiety (as  
13                   defined by the Secretary in section 314.3  
14                   of title 21, Code of Federal Regulations (or  
15                   any successor regulations)) that has been  
16                   previously approved in any other applica-  
17                   tion under subsection (b)(1), (b)(2), or (j)  
18                   of section 505; and

19                   “(II) that is the subject of an applica-  
20                   tion submitted under section 505(b)(1); or

21                  “(ii) or is for such a biological product—

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

1                   351(k) of the Public Health Service Act;  
2                   and

3                   ““(II) that is the subject of an applica-  
4                   tion submitted under section 351(a) of the  
5                   Public Health Service Act;”); and

6                   (5) in section 565A(a)(4) (21 U.S.C. 360bbb-  
7                   4a(a)(4)), by amending subparagraph (D) to read as  
8                   follows:

9                   “(D) is for—

10                   “(i) a human drug, no active moiety  
11                   (as defined by the Secretary in section  
12                   314.3 of title 21, Code of Federal Regula-  
13                   tions (or any successor regulations)) of  
14                   which has been approved in any other ap-  
15                   plication under section 505(b)(1); or

16                   “(ii) a biological product, no active in-  
17                   gredient of which has been approved in any  
18                   other application under section 351 of the  
19                   Public Health Service Act.”.

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

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

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

1 (B) in subsection (j)(5)(F), by repealing  
2 clause (i); and  
3 (2) in section 505A(c)(1)(A)(i)(II) (21 U.S.C.  
4 355a(c)(1)(A)(i)), by striking “(c)(3)(D)” and in-  
5 serting “(c)(3)(E)”.

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

8 Section 7002(e)(4) of the Biologics Price Competition  
9 and Innovation Act of 2009 (Public Law 111–148) is  
10 amended by adding at the end the following: “With respect  
11 to an application for a biological product submitted under  
12 section 505(b) of the Federal Food, Drug, and Cosmetic  
13 Act (21 U.S.C. 355(b)) with a filing date that is not later  
14 than September 23, 2019, and that does not receive final  
15 approval on or before March 23, 2020, such application  
16 shall be deemed to be withdrawn and the Secretary shall  
17 refund the fee paid under section 736(a)(1)(B) of the Fed-  
18 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
19 379h(a)(1)(B)). Notwithstanding any such withdrawal of  
20 the drug application, the Secretary shall consider any pre-  
21 viously conducted scientific review and accelerate review  
22 of any such subsequent application with respect to such  
23 biological product under section 351 of the Public Health  
24 Service Act (42 U.S.C. 262). The Secretary shall provide



1 additional assistance to the sponsor or manufacturer of  
2 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  
8 to any drug designated under section 526 for which  
9 an application was approved under section 505 of  
10 this Act or licensed under section 351 of the Public  
11 Health Service Act after the date of enactment of  
12 the FDA Reauthorization Act of 2017, regardless of  
13 the date of on which such drug was designated  
14 under section 526.”.

15 **SEC. 211. PROMPT APPROVAL OF DRUGS RELATED TO**  
16 **SAFETY 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**  
21 **INFORMATION 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  
2 drug omits safety information, including contra-  
3 indications, warnings, precautions, dosing, adminis-  
4 tration, or other information pertaining to safety,  
5 when the omitted safety information is protected by  
6 exclusivity under clause (iii) or (iv) of subsection  
7 (j)(5)(F), clause (iii) or (iv) of subsection (c)(3)(E),  
8 or section 527(a), or by an extension of such exclu-  
9 sivity under 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 Sec-  
13 retary shall require that the labeling of a drug ap-  
14 proved pursuant to an application submitted under  
15 subsection (b)(2) or (j) that omits safety information  
16 described in paragraph (1) include a statement of  
17 any appropriate safety information that the Sec-  
18 retary 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  
2 any other aspect of labeling protected by exclu-  
3 sivity 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  
23 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 exclusivity’, with re-  
8                   spect to a drug approved under section 505(c),  
9                   means any period of exclusivity under clause (ii),  
10                  (iii), or (iv) of section 505(c)(3)(E), clause (ii), (iii),  
11                  or (iv) of section 505(j)(5)(F), or section 505A,  
12                  505E, or 527.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 “(B) the number of times the Secretary  
22 entered into discussions concerning a disagree-  
23 ment with an application holder or holders and  
24 a summary of the decision regarding a labeling  
25 change, if any; and

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

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

6           (a) DEFINITIONS.—In this section—

7               (1) the term “commercially reasonable, market-  
8           based terms” means—

9                   (A) a nondiscriminatory price for the sale  
10                  of the covered product at or below, but not  
11                  greater than, the most recent wholesale acquisi-  
12                  tion cost for the drug, as defined in section  
13                  1847A(c)(6)(B) of the Social Security Act (42  
14                  U.S.C. 1395w–3a(c)(6)(B));

15                  (B) a schedule for delivery that results in  
16                  the transfer of the covered product to the eligi-  
17                  ble product developer consistent with the timing  
18                  under subsection (b)(2)(A)(iv); and

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

21           (2) the term “covered product”—

22               (A) means—

23                   (i) any drug approved under sub-  
24                  section (c) or (j) of section 505 of the Fed-  
25                  eral Food, Drug, and Cosmetic Act (21

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

5 (ii) any combination of a drug or bio-  
6 logical product described in clause (i); or

7 (iii) when reasonably necessary to  
8 support approval of an application under  
9 section 505 of the Federal Food, Drug,  
10 and Cosmetic Act (21 U.S.C. 355), or sec-  
11 tion 351 of the Public Health Service Act  
12 (42 U.S.C. 262), as applicable, or other-  
13 wise meet the requirements for approval  
14 under either such section, any product, in-  
15 cluding any device, that is marketed or in-  
16 tended for use with such a drug or biologi-  
17 cal product; and

18 (B) does not include any drug or biological  
19 product that appears on the drug shortage list  
20 in effect under section 506E of the Federal  
21 Food, Drug, and Cosmetic Act (21 U.S.C.  
22 356e), unless—

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

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

3 (ii) the Secretary determines that in-  
4 clusion of the drug or biological product as  
5 a covered product is likely to contribute to  
6 alleviating or preventing a shortage.

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

10 (4) the term “eligible product developer” means  
11 a person that seeks to develop a product for ap-  
12 proval pursuant to an application for approval under  
13 subsection (b)(2) or (j) of section 505 of the Federal  
14 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or  
15 for licensing pursuant to an application under sec-  
16 tion 351(k) of the Public Health Service Act (42  
17 U.S.C. 262(k));

18 (5) the term “license holder” means the holder  
19 of an application approved under subsection (c) or  
20 (j) of section 505 of the Federal Food, Drug, and  
21 Cosmetic Act (21 U.S.C. 355) or the holder of a li-  
22 cense under subsection (a) or (k) of section 351 of  
23 the Public Health Service Act (42 U.S.C. 262) for  
24 a covered product;

1           (6) the term “REMS” means a risk evaluation  
2 and mitigation strategy under section 505–1 of the  
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
4 355–1);

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

9           (8) the term “Secretary” means the Secretary  
10 of Health and Human Services;

11           (9) the term “single, shared system of elements  
12 to assure safe use” means a single, shared system  
13 of elements to assure safe use under section 505–  
14 1(f) of the Federal Food, Drug, and Cosmetic Act  
15 (21 U.S.C. 355–1(f)); and

16           (10) the term “sufficient quantities” means an  
17 amount of a covered product that the eligible prod-  
18 uct developer determines allows it to—

19                   (A) conduct testing to support an applica-  
20 tion under—

21                           (i) subsection (b)(2) or (j) of section  
22 505 of the Federal Food, Drug, and Cos-  
23 metic Act (21 U.S.C. 355); or

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

4 (B) fulfill any regulatory requirements re-  
5 lating to approval of such an application.

6 (b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFI-  
7 CIENT QUANTITIES OF A COVERED PRODUCT.—

8 (1) IN GENERAL.—An eligible product developer  
9 may bring a civil action against the license holder  
10 for a covered product seeking relief under this sub-  
11 section in an appropriate district court of the United  
12 States alleging that the license holder has declined  
13 to provide sufficient quantities of the covered prod-  
14 uct to the eligible product developer on commercially  
15 reasonable, market-based terms.

16 (2) ELEMENTS.—

17 (A) IN GENERAL.—To prevail in a civil ac-  
18 tion brought under paragraph (1), an eligible  
19 product developer shall prove, by a preponder-  
20 ance of the evidence—

21 (i) that—

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

24 (II) if the covered product is sub-  
25 ject to a REMS with ETASU—



1 (aa) the eligible product de-  
2 veloper has obtained a covered  
3 product authorization from the  
4 Secretary in accordance with sub-  
5 paragraph (B); and

6 (bb) the eligible product de-  
7 veloper has provided a copy of  
8 the covered product authorization  
9 to the license holder;

10 (ii) that, as of the date on which the  
11 civil action is filed, the product developer  
12 has not obtained sufficient quantities of  
13 the covered product on commercially rea-  
14 sonable, market-based terms;

15 (iii) that the eligible product developer  
16 has submitted a written request to pur-  
17 chase sufficient quantities of the covered  
18 product to the license holder, and such re-  
19 quest—

20 (I) was sent to a named cor-  
21 porate officer of the license holder;

22 (II) was made by certified or reg-  
23 istered mail with return receipt re-  
24 quested;

1 (III) specified an individual as  
2 the point of contact for the license  
3 holder to direct communications re-  
4 lated to the sale of the covered prod-  
5 uct to the eligible product developer  
6 and a means for electronic and writ-  
7 ten communications with that indi-  
8 vidual; and

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

13 (iv) that the license holder has not de-  
14 livered to the eligible product developer  
15 sufficient quantities of the covered product  
16 on commercially reasonable, market-based  
17 terms—

18 (I) for a covered product that is  
19 not subject to a REMS with ETASU,  
20 by the date that is 31 days after the  
21 date on which the license holder re-  
22 ceived the request for the covered  
23 product; and

1 (II) for a covered product that is  
2 subject to a REMS with ETASU, by  
3 31 days after the later of—

4 (aa) the date on which the  
5 license holder received the re-  
6 quest for the covered product; or

7 (bb) the date on which the  
8 license holder received a copy of  
9 the covered product authorization  
10 issued by the Secretary in ac-  
11 cordance with subparagraph (B).

12 (B) AUTHORIZATION FOR COVERED PROD-  
13 UCT SUBJECT TO A REMS WITH ETASU.—

14 (i) REQUEST.—An eligible product de-  
15 veloper may submit to the Secretary a  
16 written request for the eligible product de-  
17 veloper to be authorized to obtain suffi-  
18 cient quantities of an individual covered  
19 product subject to a REMS with ETASU.

20 (ii) AUTHORIZATION.—Not later than  
21 120 days after the date on which a request  
22 under clause (i) is received, the Secretary  
23 shall, by written notice, authorize the eligi-  
24 ble product developer to obtain sufficient  
25 quantities of an individual covered product

1 subject to a REMS with ETASU for pur-  
2 poses of—

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

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

11 (aa)(AA) submitted proto-  
12 cols, informed consent docu-  
13 ments, and informational mate-  
14 rials for testing that include pro-  
15 tections that provide safety pro-  
16 tections comparable to those pro-  
17 vided by the REMS for the cov-  
18 ered product; or

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

22 (bb) met any other require-  
23 ments the Secretary may estab-  
24 lish.

1 (iii) NOTICE.—A covered product au-  
2 thorization issued under this subparagraph  
3 shall state that the provision of the covered  
4 product by the license holder under the  
5 terms of the authorization will not be a  
6 violation of the REMS for the covered  
7 product.

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

12 (A) that, on the date on which the eligible  
13 product developer requested to purchase suffi-  
14 cient quantities of the covered product from the  
15 license holder—

16 (i) neither the license holder nor any  
17 of its agents, wholesalers, or distributors  
18 was engaged in the manufacturing or com-  
19 mercial marketing of the covered product;  
20 and

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

1 product developer on commercially reason-  
2 able, 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  
8 restrictions, explicit or implicit, on its  
9 agents, distributors, or wholesalers to sell  
10 covered products to eligible product devel-  
11 opers; and

12 (iii) the covered product can be pur-  
13 chased by the eligible product developer in  
14 sufficient quantities on commercially rea-  
15 sonable, market-based terms from the  
16 agents, distributors, or wholesalers of the  
17 license holder; or

18 (C) that the license holder made an offer  
19 to the individual specified pursuant to para-  
20 graph (2)(A)(iii)(III), by a means of commu-  
21 nication (electronic, written, or both) specified  
22 pursuant to such paragraph, to sell sufficient  
23 quantities of the covered product to the eligible  
24 product developer at commercially reasonable  
25 market-based 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  
4 which the license holder received the re-  
5 quest for the covered product, and the eli-  
6 gible product developer did not accept such  
7 offer by the date that is 7 days after the  
8 date on which the eligible product devel-  
9 oper received such offer from the license  
10 holder; or

11 (ii) for a covered product that is sub-  
12 ject to a REMS with ETASU, by the date  
13 that is 20 days after the date on which the  
14 license holder received the request for the  
15 covered product, and the eligible product  
16 developer did not accept such offer by the  
17 date that is 10 days after the date on  
18 which the eligible product developer re-  
19 ceived such offer from the license holder.

20 (4) REMEDIES.—

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

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

1 delay sufficient quantities of the covered  
2 product on commercially reasonable, mar-  
3 ket-based terms;

4 (ii) award to the eligible product de-  
5 veloper reasonable attorney's fees and costs  
6 of the civil action; and

7 (iii) award to the eligible product de-  
8 veloper a monetary amount sufficient to  
9 deter the license holder from failing to pro-  
10 vide eligible product developers with suffi-  
11 cient quantities of a covered product on  
12 commercially reasonable, market-based  
13 terms, if the court finds, by a preponder-  
14 ance of the evidence—

15 (I) that the license holder delayed  
16 providing sufficient quantities of the  
17 covered product to the eligible product  
18 developer without a legitimate busi-  
19 ness justification; or

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

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





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

8           (c) LIMITATION OF LIABILITY.—A license holder for  
9           a covered product shall not be liable for any claim under  
10          Federal, State, or local law arising out of the failure of  
11          an eligible product developer to follow adequate safeguards  
12          to assure safe use of the covered product during develop-  
13          ment or testing activities described in this section, includ-  
14          ing transportation, handling, use, or disposal of the cov-  
15          ered product by the eligible product developer.

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

20               “(1) PROVISION OF SAMPLES NOT A VIOLATION OF  
21          STRATEGY.—The provision of samples of a covered prod-  
22          uct to an eligible product developer (as those terms are  
23          defined in section 214(a) of the Lower Health Care Costs  
24          Act) shall not be considered a violation of the require-

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

3 (e) RULE OF CONSTRUCTION.—

4 (1) DEFINITION.—In this subsection, the term  
5 “antitrust laws”—

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

9 (B) includes section 5 of the Federal  
10 Trade Commission Act (15 U.S.C. 45) to the  
11 extent that such section applies to unfair meth-  
12 ods of competition.

13 (2) ANTITRUST LAWS.—Nothing in this section  
14 shall be construed to limit the operation of any pro-  
15 vision of the antitrust laws.

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

20 (1) in subsection (g)(4)(B)—

21 (A) in clause (i) by striking “or” after the  
22 semicolon;

23 (B) in clause (ii) by striking the period at  
24 the end and inserting “; or”; and

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

1           “(iii) accommodate different, com-  
2           parable aspects of the elements to assure  
3           safe use for a drug that is the subject of  
4           an application under section 505(j), and  
5           the applicable listed drug.”;

6           (2) in subsection (i)(1), by striking subpara-  
7           graph (C) and inserting the following:

8           “(C)(i) Elements to assure safe use, if re-  
9           quired under subsection (f) for the listed drug,  
10          which, subject to clause (ii), for a drug that is  
11          the subject of an application under section  
12          505(j) may use—

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

15               “(II) a different, comparable aspect of  
16               the elements to assure safe use under sub-  
17               section (f).

18           “(ii) The Secretary may require a drug  
19           that is the subject of an application under sec-  
20           tion 505(j) and the listed drug to use a single,  
21           shared system under subsection (f), if the Sec-  
22           retary determines that no different, comparable  
23           aspect of the elements to assure safe use could  
24           satisfy the requirements of subsection (f).”;

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

3           “(3) SHARED REMS.—If the Secretary ap-  
4 proves, in accordance with paragraph (1)(C)(i)(II), a  
5 different, comparable aspect of the elements to as-  
6 sure safe use under subsection (f) for a drug that  
7 is the subject of an abbreviated new drug application  
8 under section 505(j), the Secretary may require that  
9 such different comparable aspect of the elements to  
10 assure safe use can be used with respect to any  
11 other drug that is the subject of an application  
12 under section 505(j) or 505(b) that references the  
13 same listed drug.”; and

14           (4) by adding at the end the following:

15           “(m) SEPARATE REMS.—When used in this section,  
16 the terms ‘different, comparable aspect of the elements to  
17 assure safe use’ or ‘different, comparable approved risk  
18 evaluation and mitigation strategies’ means a risk evalua-  
19 tion and mitigation strategy for a drug that is the subject  
20 of an application under section 505(j) that uses different  
21 methods or operational means than the strategy required  
22 under subsection (a) for the applicable listed drug, or  
23 other application under section 505(j) with the same such  
24 listed drug, but achieves the same level of safety as such  
25 strategy.”.

1 (g) RULE OF CONSTRUCTION.—Nothing in this sec-  
2 tion, the amendments made by this section, or in section  
3 505–1 of the Federal Food, Drug, and Cosmetic Act (21  
4 U.S.C. 355–1), shall be construed as—

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

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

## 13 **TITLE III—IMPROVING TRANS-** 14 **PARENCY IN HEALTH CARE**

### 15 **SEC. 301. INCREASING TRANSPARENCY BY REMOVING GAG** 16 **CLAUSES ON PRICE AND QUALITY INFORMA-** 17 **TION.**

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

1 **“SEC. 2729B. INCREASING TRANSPARENCY BY REMOVING**  
2 **GAG CLAUSES ON PRICE AND QUALITY IN-**  
3 **FORMATION.**

4 “(a) INCREASING PRICE AND QUALITY TRANS-  
5 PARENCY FOR PLAN SPONSORS AND GROUP AND INDI-  
6 VIDUAL MARKET AND CONSUMERS.—

7 “(1) GROUP HEALTH PLANS.—A group health  
8 plan or health insurance issuer offering group health  
9 insurance coverage may not enter into an agreement  
10 with a health care provider, network or association  
11 of providers, third-party administrator, or other  
12 service provider offering access to a network of pro-  
13 viders that would directly or indirectly restrict a  
14 group health plan or health insurance issuer from—

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

20 “(B) electronically accessing de-identified  
21 claims and encounter data for each enrollee in  
22 the plan or coverage, upon request and con-  
23 sistent with the privacy regulations promul-  
24 gated pursuant to section 264(c) of the Health  
25 Insurance Portability and Accountability Act,  
26 the amendments to this Act made by the Ge-

1 netic Information Nondiscrimination Act of  
2 2008, and the Americans with Disabilities Act  
3 of 1990, with respect to the applicable health  
4 plan or health insurance coverage, including, on  
5 a per claim basis—

6 “(i) financial information, such as the  
7 allowed amount, or any other claim-related  
8 financial obligations included in the pro-  
9 vider contract;

10 “(ii) provider information, including  
11 name and clinical designation;

12 “(iii) service codes; or

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

16 “(C) sharing data described in subpara-  
17 graph (A) or (B) with a business associate as  
18 defined in section 160.103 of title 45, Code of  
19 Federal Regulations (or successor regulations),  
20 consistent with the privacy regulations promul-  
21 gated pursuant to section 264(c) of the Health  
22 Insurance Portability and Accountability Act,  
23 the amendments to this Act made by the Ge-  
24 netic Information Nondiscrimination Act of



1           2008, and the Americans with Disabilities Act  
2           of 1990.

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

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

16                 “(B) sharing, for plan design, plan admin-  
17                 istration, and plan, financial, legal, and quality  
18                 improvement activities, data described in sub-  
19                 paragraph (A) with a business associate as de-  
20                 fined in section 160.103 of title 45, Code of  
21                 Federal Regulations (or successor regulations),  
22                 consistent with the privacy regulations promul-  
23                 gated pursuant to section 264(c) of the Health  
24                 Insurance Portability and Accountability Act,  
25                 the amendments to this Act made by the Ge-

1           netic Information Nondiscrimination Act of  
2           2008, and the Americans with Disabilities Act  
3           of 1990.

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

11          “(4) ATTESTATION.—A group health plan or a  
12          health insurance issuer offering group or individual  
13          health insurance coverage shall annually submit to,  
14          as applicable, the applicable authority described in  
15          section 2723 or the Secretary of Labor, an attesta-  
16          tion that such plan or issuer is in compliance with  
17          the requirements of this subsection.

18          “(5) RULE OF CONSTRUCTION.—Nothing in  
19          this section shall be construed to otherwise limit  
20          group health plan, plan sponsor, or health insurance  
21          issuer access to data currently permitted under the  
22          privacy regulations promulgated pursuant to section  
23          264(c) of the Health Insurance Portability and Ac-  
24          countability Act, the amendments to this Act made  
25          by the Genetic Information Nondiscrimination Act of

1       2008, and the Americans with Disabilities Act of  
2       1990.”.

3       **SEC. 302. BANNING ANTICOMPETITIVE TERMS IN FACILITY**  
4                   **AND INSURANCE CONTRACTS THAT LIMIT AC-**  
5                   **CESS TO HIGHER QUALITY, LOWER COST**  
6                   **CARE.**

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

10       “(b) PROTECTING HEALTH PLANS NETWORK DE-  
11       SIGN FLEXIBILITY.—

12               “(1) IN GENERAL.—A group health plan or a  
13       health insurance issuer offering group or individual  
14       health insurance coverage shall not enter into an  
15       agreement with a provider, network or association of  
16       providers, or other service provider offering access to  
17       a network of service providers if such agreement, di-  
18       rectly or indirectly—

19               “(A) restricts the group health plan or  
20       health insurance issuer from—

21                   “(i) directing or steering enrollees to  
22                   other health care providers; or

23                   “(ii) offering incentives to encourage  
24                   enrollees to utilize specific health care pro-  
25                   viders; or

1           “(B) requires the group health plan or  
2 health insurance issuer to enter into any addi-  
3 tional contract with an affiliate of the provider,  
4 such as an affiliate of the provider, as a condi-  
5 tion of entering into a contract with such pro-  
6 vider;

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

11           “(D) restricts other group health plans or  
12 health insurance issuers not party to the con-  
13 tract from paying a lower rate for items or  
14 services than the contracting plan or issuer  
15 pays for such items or services.

16           “(2) ADDITIONAL REQUIREMENT FOR SELF-IN-  
17 SURED PLANS.—A self-insured group health plan  
18 shall not enter into an agreement with a provider,  
19 network or association of providers, third-party ad-  
20 ministrator, or other service provider offering access  
21 to a network of providers if such agreement directly  
22 or indirectly requires the group health plan to cer-  
23 tify, attest, or otherwise confirm in writing that the  
24 group health plan is bound by restrictive contracting  
25 terms between the service provider and a third-party

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

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

8 “(A) a health maintenance organization  
9 (as defined in section 2791(b)(3)), if such  
10 health maintenance organization operates pri-  
11 marily through exclusive contracts with multi-  
12 specialty physician groups, nor to any arrange-  
13 ment between such a health maintenance orga-  
14 nization and its affiliates; or

15 “(B) a value-based network arrangement,  
16 such as an exclusive provider network, account-  
17 able care organization, center of excellence, a  
18 provider sponsored health insurance issuer that  
19 operates primarily through aligned multi-spe-  
20 cialty physician group practices or integrated  
21 health systems, or such other similar network  
22 arrangements as determined by the Secretary  
23 through rulemaking.

24 “(4) ATTESTATION.—A group health plan or  
25 health insurance issuer offering group or individual

1 health insurance coverage shall annually submit to,  
2 as applicable, the applicable authority described in  
3 section 2723 or the Secretary of Labor, an attesta-  
4 tion that such plan or issuer is in compliance with  
5 the requirements of this subsection.

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

13 “(d) REGULATIONS.—The Secretary, not later than  
14 1 year after the date of enactment of the Lower Health  
15 Care Costs Act, shall promulgate regulations to carry out  
16 this section.

17 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-  
18 tion shall be construed to limit network design or cost or  
19 quality initiatives by a group health plan or health insur-  
20 ance issuer, including accountable care organizations, ex-  
21 clusive provider organizations, networks that tier providers  
22 by cost or quality or steer enrollees to centers of excel-  
23 lence, or other pay-for-performance programs.

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

1 compliance with the antitrust laws, as defined in sub-  
2 section (a) of the first section of the Clayton Act (15  
3 U.S.C. 12(a)).”.

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

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

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

20 **“SEC. 2796. DESIGNATION OF A NONGOVERNMENTAL, NON-**  
21 **PROFIT TRANSPARENCY ORGANIZATION TO**  
22 **LOWER AMERICANS’ HEALTH CARE COSTS.**

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

1 Act, shall enter into a contract with a nonprofit entity to  
2 support the establishment and maintenance of a database  
3 that receives and utilizes health care claims information  
4 and related information and issues reports that are avail-  
5 able to the public and authorized users, and are submitted  
6 to the Department of Health and Human Services.

7 “(b) REQUIREMENTS.—

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

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

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

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

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

22 “(iv) enable purchasers, including em-  
23 ployers, employee organizations, and health  
24 plans, to develop value-based purchasing  
25 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; BREACH NOTIFI-  
15                   CATIONS.—

16                   “(A) REGULATIONS.—

17                   “(i) IN GENERAL.—The Secretary  
18                   shall issue regulations prescribing the ex-  
19                   tent to which, and the manner in which,  
20                   the following rules (and any successors of  
21                   such rules) shall apply to the activities  
22                   under this section of an entity receiving a  
23                   contract under subsection (a):

24                   “(I) The Privacy Rule under part  
25                   160 and subparts A and E of part

1 164 of title 45, Code of Federal Regu-  
2 lations (or any successor regulations).

3 “(II) The Security Rule under  
4 part 160 and subparts A and C of  
5 part 164 of such title 45 (or any suc-  
6 cessor regulations).

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

11 “(ii) SUPPLEMENTAL REGULA-  
12 TIONS.—In order to ensure data privacy  
13 and security and the notification of  
14 breaches, the Secretary may issue such  
15 supplemental regulations on the subjects of  
16 the rules listed under clause (i) as the Sec-  
17 retary determines appropriate to address  
18 differences between the activities described  
19 by this section and the activities covered by  
20 such rules.

21 “(B) ENFORCEMENT.—Section 1176 of  
22 Social Security Act shall apply with respect to  
23 a violation of this paragraph in the same man-  
24 ner such section 1176 applies to a violation of  
25 part C of title XI of the Social Security Act,

1 and the Secretary may include in the regula-  
2 tions promulgated under this section provisions  
3 to apply such section to this paragraph.

4 “(C) PROCEDURE.—

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

10 “(ii) AUTHORITY TO USE INTERIM  
11 FINAL PROCEDURES.—The Secretary may  
12 make such initial set of regulations effec-  
13 tive and final immediately upon issuance,  
14 on an interim basis, and provide for a pe-  
15 riod of public comment on such initial set  
16 of regulations after the date of publication.

17 “(D) REQUIREMENTS OF ENTITY.—The  
18 entity receiving the contract under this section  
19 shall—

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

23 “(ii) 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 “(iii) maintain effective security  
4 standards for transferring data or making  
5 data available to authorized users;

6 “(iv) 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; and

10 “(v) 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

15 “(3) CONSULTATION.—

16 “(A) ADVISORY COMMITTEE.—Not later  
17 than 180 days after the date of enactment of  
18 the Lower Health Care Costs Act, the Secretary  
19 shall convene an Advisory Committee (referred  
20 to in this section as the ‘Committee’), con-  
21 sisting of 13 members, to advise the Secretary,  
22 the contracting entity, and Congress on the es-  
23 tablishment, operations, and use of the data-  
24 base established under this section.

25 “(B) MEMBERSHIP.—

1                   “(i) APPOINTMENT.—In accordance  
2                   with clause (ii), the Secretary, in consulta-  
3                   tion with the Secretary of Labor and the  
4                   Comptroller General of the United States  
5                   shall, not later than 180 days after the  
6                   date of enactment of the Lower Health  
7                   Care Costs Act, appoint members to the  
8                   Committee who have distinguished them-  
9                   selves in the fields of health services re-  
10                  search, health economics, health  
11                  informatics, or the governance of State all-  
12                  payer claims databases, or who represent  
13                  organizations likely to submit data to or  
14                  use the database, including patients, em-  
15                  ployers, or employee organizations that  
16                  sponsor group health plans, health care  
17                  providers, health insurance issuers, or  
18                  third-party administrators of group health  
19                  plans. Such members shall serve 3-year  
20                  terms on a staggered basis. Vacancies on  
21                  the Committee shall be filled by appoint-  
22                  ment consistent with this subsection not  
23                  later than 3 months after the vacancy  
24                  arises.

1                   “(ii) COMPOSITION.—In accordance  
2 with clause (i)—

3                   “(I) the Secretary, in consulta-  
4 tion with the Secretary of Labor, shall  
5 appoint to the Committee—

6                   “(aa) 1 member selected by  
7 the Secretary, in coordination  
8 with the Secretary of Labor, to  
9 serve as the chair of the Com-  
10 mittee;

11                   “(bb) the Assistant Sec-  
12 retary for Planning and Evalua-  
13 tion of the Department of Health  
14 and Human Services, or a des-  
15 ignee of such Assistant Sec-  
16 retary;

17                   “(cc) 1 representative of the  
18 Centers for Medicare & Medicaid  
19 Services;

20                   “(dd) 1 representative of the  
21 Agency for Health Research and  
22 Quality;

23                   “(ee) 1 representative of the  
24 Office for Civil Rights of the De-  
25 partment of Health and Human

1 Services with expertise in data  
2 privacy and security;

3 “(ff) 1 representative of the  
4 National Center for Health Sta-  
5 tistics; and

6 “(gg) 1 representative of the  
7 Employee Benefits and Security  
8 Administration of the Depart-  
9 ment of Labor; and

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

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

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

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

22 “(dd) 1 consumer advocate;  
23 and

24 “(ee) 2 additional members.

25 “(C) DUTIES.—The Committee shall—



1                   “(i) advise the Secretary on the man-  
2                   agement of the contract under subsection  
3                   (a);

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

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

10                  “(II) best practices with respect  
11                  to de-identification of data, as appro-  
12                  priate;

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

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

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

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

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

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

12 “(vi) establish objectives for research  
13 and public reporting.

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

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

25 “(c) CONTRACT REQUIREMENTS.—

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

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

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

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

17                  “(C) agree to comply with any require-  
18                  ments imposed under the rulemaking described  
19                  in subsection (d)(4)(A).

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

23                   “(A) health care claims data collection, ag-  
24                   gregation, quality assurance, analysis, and secu-  
25                   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, and any as-  
5 sociated code or algorithms, to a new entity in the  
6 event of contract termination.

7 “(d) RECEIVING HEALTH INFORMATION.—

8 “(1) REQUIREMENTS.—

9 “(A) IN GENERAL.—The Secretary of  
10 Labor shall ensure that the applicable self-in-  
11 sured group health plan, through its third-party  
12 administrator, pharmacy benefit manager, or  
13 other entity designated by the group health  
14 plan, as applicable, electronically submits all  
15 claims data with respect to the plan, pursuant  
16 to subparagraph (B).

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

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

1 transactions described in subparagraphs  
2 (A) and (E) of section 1173(a)(2) of the  
3 Social Security Act, including all data ele-  
4 ments normally present in such trans-  
5 actions when adjudicated, and enrollment  
6 information;

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

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

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

17 “(i) establish a process under which  
18 data is de-identified consistent with the de-  
19 identification requirements under section  
20 164.514 of title 45, Code of Federal Regu-  
21 lations (or any successor regulations),  
22 while retaining the ability to link data lon-  
23 gitudinally for the purposes of research on  
24 cost and quality, and the ability to com-

1           plete risk adjustment and geographic anal-  
2           ysis;

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

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

15           “(iv) ensure that individually identifi-  
16           able data is encrypted, in accordance with  
17           guidance issued by the Secretary under  
18           section 13402(h)(2) of the HITECH Act.

19           “(2) APPLICABLE SELF-INSURED GROUP  
20           HEALTH PLAN.—For purposes of paragraph (1), a  
21           self-insured group health plan is an applicable self-  
22           insured group health plan if such plan is self-admin-  
23           istered, or is administered by a third-party plan ad-  
24           ministrator that meets 1 or both of the following cri-  
25           teria:

1           “(A) Administers health, medical, or phar-  
2           macy benefits for more than 50,000 enrollees.

3           “(B) Is one of the 5 largest administrators  
4           or issuers of self-insured group health plans in  
5           a State in which such administrator operates,  
6           as measured by the aggregate number of enroll-  
7           ees in plans administered by such administrator  
8           in such State, as determined by the Secretary.

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

18          “(4) RECEIVING OTHER INFORMATION.—

19                 “(A) MEDICARE DATA.—The Secretary,  
20                 through rulemaking, shall ensure that the data  
21                 made available to such entity is available to  
22                 qualified entities under section 1874(e) of the  
23                 Social Security Act is made available to the en-  
24                 tity awarded a contract under subsection (a).



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

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

10          “(e) USES OF INFORMATION.—

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

17           “(2) AUTHORIZATION OF USERS.—

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

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

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

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

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

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

18 “(C) REQUIREMENTS.—

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

1 reidentify and disclose individually identifi-  
2 able health information and proprietary fi-  
3 nancial information.

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

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

1                   “(iv) NON-CUSTOMIZED REPORTS.—

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

7                   “(f) FUNDING.—

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

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

19                  “(g) ANNUAL REPORT.—

20                  “(1) SUBMISSION.—On each of the dates de-  
21                  scribed in paragraph (2), the entity receiving the  
22                  contract under subsection (a) shall submit to Con-  
23                  gress, the Secretary of Health and Human Services,  
24                  and the Secretary of Labor and publish online for

1 access by the general public, a report containing a  
2 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) DATES DESCRIBED.—The reports de-  
13 scribed in paragraph (1) shall be submitted—

14 “(A) not later than 3 years after the date  
15 of enactment of the Lower Health Care Costs  
16 Act;

17 “(B) the later of 1 year after the date that  
18 is 3 years after such date of enactment or  
19 March 1 of the year after the date that is 3  
20 years after such date of enactment; and

21 “(C) March 1 of each year thereafter.

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

1 ongoing basis to promote the objectives of this sec-  
2 tion.

3 “(h) GRANTS TO STATES.—

4 “(1) IN GENERAL.—The Secretary, in consulta-  
5 tion with the Secretary of Labor, may award grants  
6 to States for the purpose of establishing and main-  
7 taining State all-payer claims databases that im-  
8 prove transparency of data in order to meet the  
9 goals of subsection (a)(1).

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

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

19 “(i) EXEMPTION FROM PUBLIC DISCLOSURE.—

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

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

1 shall not be subject to discovery or admission as  
2 public information, or evidence in judicial or admin-  
3 istrative proceedings without consent of the affected  
4 parties.

5 “(j) DEFINITIONS.—

6 “(1) INDIVIDUALLY IDENTIFIABLE HEALTH IN-  
7 FORMATION.—The term ‘individually identifiable  
8 health information’ has the meaning given such term  
9 in section 1171(6) of the Social Security Act.

10 “(2) PROPRIETARY FINANCIAL INFORMATION.—

11 The term ‘proprietary financial information’ means  
12 data that would disclose the terms of a specific con-  
13 tract between an individual health care provider or  
14 facility and a specific group health plan, Medicaid  
15 managed care organization or other managed care  
16 entity, or health insurance issuer offering group or  
17 individual coverage.

18 “(k) RULE OF CONSTRUCTION.—Nothing in this sec-  
19 tion shall be construed to affect or modify enforcement  
20 of the privacy, security, or breach notification rules pro-  
21 mulgated under section 264(c) of the Health Insurance  
22 Portability and Accountability Act of 1996 (or successor  
23 regulations).”.

24 (b) GAO REPORT.—

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

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

7                   (B) the privacy and security of the infor-  
8 mation reported to the entity; and

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

11           (2) REPORTS.—Not later than 2 years after the  
12 effective date of the first contract entered into under  
13 section 2795(a) of the Public Health Service Act, as  
14 added by subsection (a), and again not later than 4  
15 years after such effective date, the Comptroller Gen-  
16 eral of the United States shall submit to Congress  
17 a report containing the results of the study con-  
18 ducted under paragraph (1), together with rec-  
19 ommendations for such legislation and administra-  
20 tive action as the Comptroller General determines  
21 appropriate.



1 **SEC. 304. PROTECTING PATIENTS AND IMPROVING THE AC-**  
2 **CURACY OF PROVIDER DIRECTORY INFOR-**  
3 **MATION.**

4 (a) IN GENERAL.—Subpart II of part A of title  
5 XXVII of the Public Health Service Act (42 U.S.C.  
6 300gg–11 et seq.), as amended by sections 301 and 302,  
7 is further 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 sec-  
14 tion, a group health plan or a health insurance  
15 issuer offering group or individual health insurance  
16 coverage shall—

17 “(A) establish business processes to ensure  
18 that all enrollees in such plan or coverage re-  
19 ceive proof of a health care provider’s network  
20 status, based on what a plan or issuer knows or  
21 could 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,  
5 and kept in the enrollee’s file for a min-  
6 imum of 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  
13 data update and that enrollees or prospective  
14 enrollees should consult the group health plan  
15 or issuer’s electronic provider directory on its  
16 website or call a specified customer service tele-  
17 phone number to obtain the most current pro-  
18 vider directory information.

19 “(2) GROUP HEALTH PLAN AND HEALTH IN-  
20 SURANCE ISSUER BUSINESS PROCESSES.—Beginning  
21 on the date that is one year after the date of enact-  
22 ment of the Lower Health Care Costs Act, a group  
23 health plan or a health insurance issuer offering  
24 group or individual health insurance coverage shall  
25 establish 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  
9           previous 6 months or the plan or issuer has  
10          been unable to verify the provider’s network  
11          participation.

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  
17                 enrollee for treatment or services provided by a  
18                 health care provider in excess of the normal cost-  
19                 sharing applied for in-network care (including any  
20                 balance bill issued by the health care provider in-  
21                 volved), if such enrollee, or health care provider re-  
22                 ferring such enrollee, demonstrates (based on the  
23                 electronic, written information described in sub-  
24                 section (a)(1)(A)(i), the oral confirmation described  
25                 in subsection (a)(1)(A)(ii), or a copy of the online

1 provider directory described in subsection  
2 (a)(1)(A)(iii) on the date the enrollee attempted to  
3 obtain the provider's network status) that the en-  
4 rollee relied on the information described in sub-  
5 section (a)(1), if the provider's network status or di-  
6 rectory information on such directory was incorrect  
7 at the time the treatment or services involved was  
8 provided.

9 “(2) REFUNDS TO ENROLLEES.—If a health  
10 care provider submits a bill to an enrollee in viola-  
11 tion of paragraph (1), and the enrollee pays such  
12 bill, the provider shall reimburse the enrollee for the  
13 full amount paid by the enrollee in excess of the in-  
14 network cost-sharing amount for the treatment or  
15 services involved, plus interest, at an interest rate  
16 determined by the Secretary.

17 “(c) PROVIDER BUSINESS PROCESSES.—A health  
18 care provider shall have in place business processes to en-  
19 sure the timely provision of provider directory information  
20 to a group health plan or a health insurance issuer offer-  
21 ing group or individual health insurance coverage to sup-  
22 port compliance by such plans or issuers with subsection  
23 (a)(1). Such providers shall submit provider directory in-  
24 formation 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  
8           content of provider directory information described  
9           in 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  
15           under subsection (c) or takes actions that prevent a  
16           group health plan or health insurance issuer from  
17           complying with subsection (a)(1) or (b) shall be sub-  
18           ject to a civil monetary penalty of not more than  
19           \$10,000 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 vio-  
2 lation 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 sub-  
18 section (a)(1); or

19 “(2) that the plan or issuer bear financial re-  
20 sponsibility, 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  
17 Public Health Service Act (42 U.S.C. 280g et seq.)  
18 is 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  
22 practitioners providing services outside of such a fa-  
23 cility, practitioners, to provide to patients a list of  
24 services rendered during the visit to such facility or  
25 practitioner, and, in the case of a facility, the name

1 of the provider for each such service, upon discharge  
2 or end of the visit or by postal or electronic commu-  
3 nication as soon as practicable and not later than 5  
4 calendar 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  
8 after 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  
12 services.

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  
19 or practitioner shall report such failure to the  
20 Secretary.

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  
9 impose civil monetary penalties of up to  
10 \$10,000 a day on any facility or practitioner  
11 that—

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

16 “(ii) submits more than 10 bills out-  
17 side of the period described in subsection  
18 (a)(2), beginning on the date on which  
19 such facility or practitioner sends the tenth  
20 such bill;

21 “(iii) fails to report to the Secretary  
22 any failure to provide lists as required  
23 under paragraph (1)(A), beginning on the  
24 date that is 45 calendar days after dis-  
25 charge or visit; or



1           (2) RULEMAKING.—Not later than 1 year after  
2           the date of enactment of this Act, the Secretary  
3           shall promulgate final regulations to define the term  
4           “extenuating circumstance” for purposes of section  
5           399V–7(c)(3)(B) of the Public Health Service Act,  
6           as added by paragraph (1).

7           (b) GROUP HEALTH PLAN AND HEALTH INSURANCE  
8           ISSUER REQUIREMENTS.—Subpart II of part A of title  
9           XXVII of the Public Health Service Act (42 U.S.C.  
10          300gg–11), as amended by section 304, is further amend-  
11          ed by adding at the end the following:

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

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

20           “(b) CLARIFICATION.—Nothing in subsection (a) pro-  
21          hibits a provider and a group health plan or health insur-  
22          ance issuer from establishing in a contract the timeline  
23          for submission by either party to the other party of billing  
24          information, adjudication, sending of remittance informa-  
25          tion, or any other coordination required between the pro-

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

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

6 **SEC. 306. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**  
7 **EFIT MANAGER SERVICES.**

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

12 **“SEC. 2729E. HEALTH PLAN OVERSIGHT OF PHARMACY**  
13 **BENEFIT MANAGER SERVICES.**

14 “(a) IN GENERAL.—A group health plan or health  
15 insurance issuer offering group health insurance coverage  
16 or an entity or subsidiary providing pharmacy benefits  
17 management services shall not enter into a contract with  
18 a drug manufacturer, distributor, wholesaler, subcon-  
19 tractor, rebate aggregator, or any associated third party  
20 that limits the disclosure of information to plan sponsors  
21 in such a manner that prevents the plan or coverage, or  
22 an entity or subsidiary providing pharmacy benefits man-  
23 agement services on behalf of a plan or coverage from  
24 making the reports described in subsection (b).

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

1           “(1) IN GENERAL.—Beginning with the first  
2           plan year that begins after the date of enactment of  
3           the Lower Health Care Costs Act, not less fre-  
4           quently than once every 6 months, a health insur-  
5           ance issuer offering group health insurance coverage  
6           or an entity providing pharmacy benefits manage-  
7           ment services on behalf of a group health plan shall  
8           submit to the plan sponsor (as defined in section  
9           3(16)(B) of the Employee Retirement Income Secu-  
10          rity Act of 1974) of such group health plan or  
11          health insurance coverage a report in accordance  
12          with this subsection and make such report available  
13          to the plan sponsor in a machine-readable format.  
14          Each such report shall include, with respect to the  
15          applicable group health plan or health insurance cov-  
16          erage—

17                   “(A) information collected from drug man-  
18                   ufacturers by such issuer or entity on the total  
19                   amount of copayment assistance dollars paid, or  
20                   copayment cards applied, that were funded by  
21                   the drug manufacturer with respect to the en-  
22                   rollees in such plan or coverage;

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

1 spect to each such drug during the reporting  
2 period—

3 “(i) the brand name, chemical entity,  
4 and National Drug Code;

5 “(ii) the number of enrollees for  
6 whom the drug was filled during the plan  
7 year, the total number of prescription fills  
8 for the drug (including original prescrip-  
9 tions and refills), and the total number of  
10 dosage units of the drug dispensed across  
11 the plan year, including whether the dis-  
12 pensing channel was by retail, mail order,  
13 or specialty pharmacy;

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

18 “(iv) the total out-of-pocket spending  
19 by enrollees on such drug, including en-  
20 rollee spending through copayments, coin-  
21 surance, and deductibles;

22 “(v) for any drug for which gross  
23 spending of the group health plan or  
24 health insurance coverage exceeded  
25 \$10,000 during the reporting period—

1                   “(I) a list of all other available  
2                   drugs in the same therapeutic cat-  
3                   egory or class, including brand name  
4                   drugs and biological products and ge-  
5                   neric drugs or biosimilar biological  
6                   products that are in the same thera-  
7                   peutic category or class; and

8                   “(II) the rationale for preferred  
9                   formulary placement of a particular  
10                  drug or drugs in that therapeutic cat-  
11                  egory or class;

12                  “(C) a list of each therapeutic category or  
13                  class of drugs that were dispensed under the  
14                  health plan or health insurance coverage during  
15                  the reporting period, and, with respect to each  
16                  such therapeutic category or class of drugs,  
17                  during the reporting period—

18                         “(i) total gross spending by the plan,  
19                         before manufacturer rebates, fees, or other  
20                         manufacturer remuneration;

21                         “(ii) the number of enrollees who  
22                         filled a prescription for a drug in that cat-  
23                         egory or class;

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

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

4 “(iv) the total out-of-pocket spending  
5 by enrollees, including enrollee spending  
6 through copayments, coinsurance, and  
7 deductibles; and

8 “(v) for each therapeutic category or  
9 class under which 3 or more drugs are in-  
10 cluded on the formulary of such plan or  
11 coverage—

12 “(I) the amount received, or ex-  
13 pected to be received, from drug man-  
14 ufacturers in rebates, fees, alternative  
15 discounts, or other remuneration—

16 “(aa) to be paid by drug  
17 manufacturers for claims in-  
18 curred during the reporting pe-  
19 riod; or

20 “(bb) that is related to utili-  
21 zation of drugs, in such thera-  
22 peutic category or class;

23 “(II) the total net spending, after  
24 deducting rebates, price concessions,  
25 alternative discounts or other remu-



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

5                   “(III) the net price per course of  
6                   treatment or 30-day supply incurred  
7                   by the health plan or health insurance  
8                   coverage and its enrollees, after man-  
9                   ufacturer rebates, fees, and other re-  
10                  muneration for drugs dispensed within  
11                  such therapeutic category or class  
12                  during the reporting period;

13                  “(D) total gross spending on prescription  
14                  drugs by the plan or coverage during the re-  
15                  porting period, before rebates and other manu-  
16                  facturer fees or remuneration;

17                  “(E) total amount received, or expected to  
18                  be received, by the health plan or health insur-  
19                  ance coverage in drug manufacturer rebates,  
20                  fees, alternative discounts, and all other remu-  
21                  neration received from the manufacturer or any  
22                  third party, other than the plan sponsor, re-  
23                  lated to utilization of drug or drug spending  
24                  under that health plan or health insurance cov-  
25                  erage during the reporting period;

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

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

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

22          “(3) DISCLOSURE AND REDISCLOSURE.—

23                 “(A) LIMITATION TO BUSINESS ASSOCI-  
24                 ATES.—A group health plan receiving a report  
25                 under paragraph (1) may disclose such informa-

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

4           “(B) CLARIFICATION REGARDING PUBLIC  
5           DISCLOSURE OF INFORMATION.—Nothing in  
6           this section prevents a health insurance issuer  
7           offering group health insurance coverage or an  
8           entity providing pharmacy benefits management  
9           services on behalf of a group health plan from  
10          placing reasonable restrictions on the public dis-  
11          closure of the information contained in a report  
12          described in paragraph (1), except that such  
13          issuer or entity may not restrict disclosure of  
14          such report to governmental agencies pursuant  
15          to an investigation or enforcement action.

16          “(C) LIMITED FORM OF REPORT.—The  
17          Secretary shall define through rulemaking a  
18          limited form of the report under paragraph (1)  
19          required of plan sponsors who are drug manu-  
20          facturers, drug wholesalers, or other direct par-  
21          ticipants in the drug supply chain, in order to  
22          prevent anti-competitive behavior.

23          “(c) LIMITATIONS ON SPREAD PRICING.—

24                  “(1) PRESCRIPTION DRUG TRANSACTIONS WITH  
25                  PHARMACIES INDEPENDENT OF THE ISSUER OR

1 PHARMACY BENEFITS MANAGER.—If the pharmacy  
2 that dispenses a prescription drug to an enrollee in  
3 a group health plan or group or individual health in-  
4 surance coverage is not wholly or partially-owned by  
5 such plan, such issuer, or an entity providing phar-  
6 macy benefit management services under such plan  
7 or coverage, such plan, issuer, or entity shall not  
8 charge the plan, issuer, or enrollee a price for such  
9 prescription drug that exceeds the price paid to the  
10 pharmacy, excluding penalties paid by pharmacies to  
11 such plan, issuer, or entity.

12 “(2) INTRA-COMPANY PRESCRIPTION DRUG  
13 TRANSACTIONS.—If the mail order, specialty, or re-  
14 tail pharmacy that dispenses a prescription drug to  
15 an enrollee in a group health plan or health insur-  
16 ance coverage is wholly or partially owned by, and  
17 submits claims to, such health insurance issuer or  
18 an entity providing pharmacy benefit management  
19 services under a group health plan or group or indi-  
20 vidual health insurance coverage, the price charged  
21 for such drug by such pharmacy to such group  
22 health plan or health insurance issuer offering group  
23 or individual health insurance coverage may not ex-  
24 ceed the lesser of—

1           “(A) the amount paid to the pharmacy for  
2           acquisition of the drug; or

3           “(B) the median price charged to the  
4           group health plan or health insurance issuer  
5           when the same drug is dispensed to enrollees in  
6           the plan or coverage by other similarly-situated  
7           pharmacies not wholly or partially owned by the  
8           health insurance issuer or entity providing  
9           pharmacy benefits management services, as de-  
10          scribed in paragraph (1).

11          “(3) SUPPLEMENTARY REPORTING FOR INTRA-  
12          COMPANY PRESCRIPTION DRUG TRANSACTIONS.—A  
13          health insurance issuer of group health insurance  
14          coverage or an entity providing pharmacy benefits  
15          management services under a group health plan or  
16          group health insurance coverage that conducts  
17          transactions with a wholly or partially-owned phar-  
18          macy, as described in paragraph (2), shall submit,  
19          together with the report under subsection (b), a sup-  
20          plementary report every 6 months to the plan spon-  
21          sor that includes—

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

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

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

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

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

20 “(ii) the median amount charged to  
21 the plan or coverage, per course of treat-  
22 ment or 30-day supply, including amounts  
23 paid by the enrollee, when the same drug  
24 is dispensed by other pharmacies that are  
25 not wholly or partially-owned by the issuer

1 or entity and that are included in the  
2 pharmacy network of that plan or cov-  
3 erage;

4 “(iii) the interquartile range of the  
5 costs, per course of treatment or 30-day  
6 supply, including amounts paid by the en-  
7 rollee, when the same drug is dispensed by  
8 other pharmacies that are not wholly or  
9 partially-owned by the issuer or entity and  
10 that are included in the pharmacy network  
11 of that plan or coverage;

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

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

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

1 all other remuneration received from a pharma-  
2 ceutical manufacturer, distributor or any other third  
3 party, that are related to utilization of drugs under  
4 such health plan or health insurance coverage, to the  
5 group health plan.

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

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

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

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

20 “(D) returned to the issuer or entity pro-  
21 viding pharmaceutical benefit management  
22 services by the group health plan if audits by  
23 such issuer or entity indicate that the amounts  
24 received are incorrect after such amounts have  
25 been paid to the group health plan.



1           “(3) AUDIT OF REBATE CONTRACTS.—A phar-  
2           macy benefits manager, a third-party administrator  
3           of a group health plan, a health insurance issuer of-  
4           fering group health insurance coverage, or an entity  
5           providing pharmacy benefits management services  
6           under such health plan or health insurance coverage  
7           shall make rebate contracts with drug manufactur-  
8           ers available for audit by such plan sponsor or des-  
9           ignated third-party, subject to confidentiality agree-  
10          ments to prevent re-disclosure of such contracts.

11          “(e) ENFORCEMENT.—

12           “(1) IN GENERAL.—The Secretary, in consulta-  
13          tion with the Secretary of Labor and the Secretary  
14          of the Treasury, shall enforce this section.

15           “(2) FAILURE TO PROVIDE TIMELY INFORMA-  
16          TION.—A health insurance issuer or an entity pro-  
17          viding pharmacy benefit management services that  
18          violates subsection (a), fails to provide information  
19          required under subsection (b), engages in spread  
20          pricing as defined in subsection (c), or fails to com-  
21          ply with the requirements of subsection (d), or a  
22          drug manufacturer that fails to provide information  
23          under subsection (b)(1)(A), in a timely manner shall  
24          be subject to a civil monetary penalty in the amount  
25          of \$10,000 for each day during which such violation

1 continues or such information is not disclosed or re-  
2 ported.

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

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

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

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

7 “(g) DEFINITIONS.—In this section—

8 “(1) the term ‘similarly situated pharmacy’  
9 means, with respect to a particular pharmacy, an-  
10 other pharmacy that is approximately the same size  
11 (as measured by the number of prescription drugs  
12 dispensed), and that serves patients in the same geo-  
13 graphical area, whether through physical locations or  
14 mail order; and

15 “(2) the term ‘wholesale acquisition cost’ has  
16 the meaning given such term in  
17 sectionb1847A(c)(6)(B) of the Social Security Act.”.

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

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

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

1 health care markets, including those relationships  
2 that—

3 (A) involve one or more—

4 (i) physician groups that practice  
5 within a hospital included in the profit- or  
6 revenue-sharing relationship, or refer pa-  
7 tients to such hospital;

8 (ii) laboratory, radiology, or pharmacy  
9 services that are delivered to privately in-  
10 sured patients of such hospital;

11 (iii) surgical services;

12 (iv) hospitals or group purchasing or-  
13 ganizations; or

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

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

20 (2) describe Federal oversight of such relation-  
21 ships, including authorities of the Department of  
22 Health and Human Services and the Federal Trade  
23 Commission to review such relationships and their  
24 potential to increase costs for patients, and identify  
25 limitations in such oversight; and

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

3           (b) REPORT.—Not later than 1 year after the date  
4 of enactment of this Act, the Comptroller General of the  
5 United States shall prepare and submit a report on the  
6 study conducted under subsection (a) to the Committee  
7 on Health, Education, Labor, and Pensions of the Senate  
8 and the Committee on Education and Labor and Com-  
9 mittee on Energy and Commerce of the House of Rep-  
10 resentatives.

11 **SEC. 308. DISCLOSURE OF DIRECT AND INDIRECT COM-**  
12 **PENSATION FOR BROKERS AND CONSULT-**  
13 **ANTS TO EMPLOYER-SPONSORED HEALTH**  
14 **PLANS AND ENROLLEES IN PLANS ON THE IN-**  
15 **DIVIDUAL MARKET.**

16           (a) GROUP HEALTH PLANS.—Section 408(b)(2) of  
17 the Employee Retirement Income Security Act of 1974  
18 (29 U.S.C. 1108(b)(2)) is amended—

19           (1) by striking “(2) Contracting or making”  
20           and inserting “(2)(A) Contracting or making”; and  
21           (2) by adding at the end the following:

22           “(B)(i) No contract or arrangement for services  
23           between a covered plan and a covered service pro-  
24           vider, and no extension or renewal of such a contract  
25           or arrangement, is reasonable within the meaning of

1       this paragraph unless the requirements of this  
2       clause are met.

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

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

6                       “(bb) The term ‘covered service provider’  
7                       means a service provider that enters into a con-  
8                       tract or arrangement with the covered plan and  
9                       reasonably expects \$1,000 (or such amount as  
10                      the Secretary may establish in regulations to  
11                      account for inflation since the date of enact-  
12                      ment of the Lower Health Care Costs Act, as  
13                      appropriate) or more in compensation, direct or  
14                      indirect, to be received in connection with pro-  
15                      viding one or more of the following services,  
16                      pursuant to the contract or arrangement, re-  
17                      gardless of whether such services will be per-  
18                      formed, or such compensation received, by the  
19                      covered service provider, an affiliate, or a sub-  
20                      contractor:

21                               “(AA) Brokerage services, for which  
22                               the covered service provider, an affiliate, or  
23                               a subcontractor reasonably expects to re-  
24                               ceive indirect compensation or direct com-  
25                               pensation described in item (dd), provided

1 to a covered plan with respect to selection  
2 of insurance products (including vision and  
3 dental), recordkeeping services, medical  
4 management vendor, benefits administra-  
5 tion (including vision and dental), stop-loss  
6 insurance, pharmacy benefit management  
7 services, wellness services, transparency  
8 tools and vendors, group purchasing orga-  
9 nization preferred vendor panels, disease  
10 management vendors and products, compli-  
11 ance services, employee assistance pro-  
12 grams, or third party administration serv-  
13 ices.

14 “(BB) Consulting, for which the cov-  
15 ered service provider, an affiliate, or a sub-  
16 contractor reasonably expects to receive in-  
17 direct compensation or direct compensation  
18 described in item (dd), related to the devel-  
19 opment or implementation of plan design,  
20 insurance or insurance product selection  
21 (including vision and dental), record-  
22 keeping, medical management, benefits ad-  
23 ministration selection (including vision and  
24 dental), stop-loss insurance, pharmacy ben-  
25 efit management services, wellness design

1 and management services, transparency  
2 tools, group purchasing organization agree-  
3 ments and services, participation in and  
4 services from preferred vendor panels, dis-  
5 ease management, compliance services, em-  
6 ployee assistance programs, or third party  
7 administration services.

8 “(cc) The term ‘affiliate’, with respect to a  
9 covered service provider, means an entity that  
10 directly or indirectly (through one or more  
11 intermediaries) controls, is controlled by, or is  
12 under common control with, such provider, or is  
13 an officer, director, or employee of, or partner  
14 in, such provider.

15 “(dd)(AA) The term ‘compensation’ means  
16 anything of monetary value, but does not in-  
17 clude non-monetary compensation valued at  
18 \$250 (or such amount as the Secretary may es-  
19 tablish in regulations to account for inflation  
20 since the date of enactment of the Lower  
21 Health Care Costs Act, as appropriate) or less,  
22 in the aggregate, during the term of the con-  
23 tract or arrangement.



1           “(BB) The term ‘direct compensation’  
2 means compensation received directly from a  
3 covered plan.

4           “(CC) The term ‘indirect compensation’  
5 means compensation received from any source  
6 other than the covered plan, the plan sponsor,  
7 the covered service provider, or an affiliate.  
8 Compensation received from a subcontractor is  
9 indirect compensation, unless it is received in  
10 connection with services performed under a con-  
11 tract or arrangement with a subcontractor.

12           “(ee) The term ‘responsible plan fiduciary’  
13 means a fiduciary with authority to cause the  
14 covered plan to enter into, or extend or renew,  
15 the contract or arrangement.

16           “(ff) The term ‘subcontractor’ means any  
17 person or entity (or an affiliate of such person  
18 or entity) that is not an affiliate of the covered  
19 service provider and that, pursuant to a con-  
20 tract or arrangement with the covered service  
21 provider or an affiliate, reasonably expects to  
22 receive \$1,000 (or such amount as the Sec-  
23 retary may establish in regulations to account  
24 for inflation since the date of enactment of the  
25 Lower Health Care Costs Act, as appropriate)

1           or more in compensation for performing one or  
2           more services described in item (bb) under a  
3           contract or arrangement with the covered plan.

4           “(II) For purposes of this subparagraph, a de-  
5           scription of compensation or cost may be expressed  
6           as a monetary amount, formula, or a per capita  
7           charge for each enrollee or, if the compensation or  
8           cost cannot reasonably be expressed in such terms,  
9           by any other reasonable method, including a disclo-  
10          sure that additional compensation may be earned  
11          but may not be calculated at the time of contract if  
12          such a disclosure includes a description of the cir-  
13          cumstances under which the additional compensation  
14          may be earned and a reasonable and good faith esti-  
15          mate if the covered service provider cannot otherwise  
16          readily describe compensation or cost and explains  
17          the methodology and assumptions used to prepare  
18          such estimate. Any such description shall contain  
19          sufficient information to permit evaluation of the  
20          reasonableness of the compensation or cost.

21          “(III) No person or entity is a ‘covered service  
22          provider’ within the meaning of subclause (I)(bb)  
23          solely on the basis of providing services as an affil-  
24          iate or a subcontractor that is performing one or  
25          more of the services described in subitem (AA) or

1 (BB) of such subclause under the contract or ar-  
2 rangement with the covered plan.

3 “(iii) A covered service provider shall disclose to  
4 a responsible plan fiduciary, in writing, the fol-  
5 lowing:

6 “(I) A description of the services to be pro-  
7 vided to the covered plan pursuant to the con-  
8 tract or arrangement.

9 “(II) If applicable, a statement that the  
10 covered service provider, an affiliate, or a sub-  
11 contractor will provide, or reasonably expects to  
12 provide, services pursuant to the contract or ar-  
13 rangement directly to the covered plan as a fi-  
14 duciary (within the meaning of section 3(21)).

15 “(III) A description of all direct compensa-  
16 tion, either in the aggregate or by service, that  
17 the covered service provider, an affiliate, or a  
18 subcontractor reasonably expects to receive in  
19 connection with the services described in sub-  
20 clause (I).

21 “(IV)(aa) A description of all indirect com-  
22 pensation that the covered service provider, an  
23 affiliate, or a subcontractor reasonably expects  
24 to receive in connection with the services de-  
25 scribed in subclause (I)—

1           “(AA) including compensation from a  
2           vendor to a brokerage firm based on a  
3           structure of incentives not solely related to  
4           the contract with the covered plan; and

5           “(BB) not including compensation re-  
6           ceived by an employee from an employer  
7           on account of work performed by the em-  
8           ployee.

9           “(bb) A description of the arrangement be-  
10          tween the payer and the covered service pro-  
11          vider, an affiliate, or a subcontractor, as appli-  
12          cable, pursuant to which such indirect com-  
13          pensation is paid.

14          “(cc) Identification of the services for  
15          which the indirect compensation will be re-  
16          ceived, if applicable.

17          “(dd) Identification of the payer of the in-  
18          direct compensation.

19          “(V) A description of any compensation  
20          that will be paid among the covered service pro-  
21          vider, an affiliate, or a subcontractor, in con-  
22          nection with the services described in subclause  
23          (I) if such compensation is set on a transaction  
24          basis (such as commissions, finder’s fees, or  
25          other similar incentive compensation based on

1 business placed or retained), including identi-  
2 fication of the services for which such com-  
3 pensation will be paid and identification of the  
4 payers and recipients of such compensation (in-  
5 cluding the status of a payer or recipient as an  
6 affiliate or a subcontractor), regardless of  
7 whether such compensation also is disclosed  
8 pursuant to subclause (III) or (IV).

9 “(VI) A description of any compensation  
10 that the covered service provider, an affiliate, or  
11 a subcontractor reasonably expects to receive in  
12 connection with termination of the contract or  
13 arrangement, and how any prepaid amounts  
14 will be calculated and refunded upon such ter-  
15 mination.

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

20 “(v)(I) A covered service provider shall disclose  
21 the information required under clauses (iii) and (iv)  
22 to the responsible plan fiduciary not later than the  
23 date that is reasonably in advance of the date on  
24 which the contract or arrangement is entered into,  
25 and extended or renewed.

1           “(II) A covered service provider shall disclose  
2           any change to the information required under clause  
3           (iii) and (iv) as soon as practicable, but not later  
4           than 60 days from the date on which the covered  
5           service provider is informed of such change, unless  
6           such disclosure is precluded due to extraordinary cir-  
7           cumstances beyond the covered service provider’s  
8           control, in which case the information shall be dis-  
9           closed as soon as practicable.

10           “(vi)(I) Upon the written request of the respon-  
11           sible plan fiduciary or covered plan administrator, a  
12           covered service provider shall furnish any other in-  
13           formation relating to the compensation received in  
14           connection with the contract or arrangement that is  
15           required for the covered plan to comply with the re-  
16           porting and disclosure requirements under this Act.

17           “(II) The covered service provider shall disclose  
18           the information required under clause (iii)(I) reason-  
19           ably in advance of the date upon which such respon-  
20           sible plan fiduciary or covered plan administrator  
21           states that it is required to comply with the applica-  
22           ble reporting or disclosure requirement, unless such  
23           disclosure is precluded due to extraordinary cir-  
24           cumstances beyond the covered service provider’s

1 control, in which case the information shall be dis-  
2 closed as soon as practicable.

3 “(vii) No contract or arrangement will fail to be  
4 reasonable under this subparagraph solely because  
5 the covered service provider, acting in good faith and  
6 with reasonable diligence, makes an error or omis-  
7 sion in disclosing the information required pursuant  
8 to clause (iii) (or a change to such information dis-  
9 closed pursuant to clause (v)(II)) or clause (vi), pro-  
10 vided that the covered service provider discloses the  
11 correct information to the responsible plan fiduciary  
12 as soon as practicable, but not later than 30 days  
13 from the date on which the covered service provider  
14 knows of such error or omission.

15 “(viii)(I) Pursuant to subsection (a), subpara-  
16 graphs (C) and (D) of section 406(a)(1) shall not  
17 apply to a responsible plan fiduciary, notwith-  
18 standing any failure by a covered service provider to  
19 disclose information required under clause (iii), if  
20 the following conditions are met:

21 “(aa) The responsible plan fiduciary did  
22 not know that the covered service provider  
23 failed or would fail to make required disclosures  
24 and reasonably believed that the covered service

1 provider disclosed the information required to  
2 be disclosed.

3 “(bb) The responsible plan fiduciary, upon  
4 discovering that the covered service provider  
5 failed to disclose the required information, re-  
6 quests in writing that the covered service pro-  
7 vider furnish such information.

8 “(cc) If the covered service provider fails  
9 to comply with a written request described in  
10 subclause (II) within 90 days of the request,  
11 the responsible plan fiduciary notifies the Sec-  
12 retary of the covered service provider’s failure,  
13 in accordance with subclauses (II) and (III).

14 “(II) A notice described in subclause (I)(cc)  
15 shall contain—

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

17 “(bb) the plan number used for the annual  
18 report on the covered plan;

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

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

23 “(ee) the name, address, phone number,  
24 and, if known, employer identification number  
25 of the covered service provider;



1           “(ff) a description of the services provided  
2           to the covered plan;

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

5           “(hh) the date on which such information  
6           was requested in writing from the covered serv-  
7           ice provider; and

8           “(ii) a statement as to whether the covered  
9           service provider continues to provide services to  
10          the plan.

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

14                 “(aa) The covered service provider’s re-  
15                 fusals to furnish the information requested by  
16                 the written request described in subclause  
17                 (I)(bb); or

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

20          “(IV) If the covered service provider fails to  
21          comply with the written request under subclause  
22          (I)(bb) within 90 days of such request, the respon-  
23          sible plan fiduciary shall determine whether to ter-  
24          minate or continue the contract or arrangement  
25          under section 404. If the requested information re-

1       lates to future services and is not disclosed promptly  
2       after the end of the 90-day period, the responsible  
3       plan fiduciary shall terminate the contract or ar-  
4       rangement as expeditiously as possible, consistent  
5       with such duty of prudence.

6               “(ix) Nothing in this subparagraph shall be  
7       construed to supersede any provision of State law  
8       that governs disclosures by parties that provide the  
9       services described in this section, except to the ex-  
10      tent that such law prevents the application of a re-  
11      quirement of this section.”.

12      (b) **APPLICABILITY OF EXISTING REGULATIONS.**—  
13      Nothing in the amendments made by subsection (a) shall  
14      be construed to affect the applicability of section  
15      2550.408b–2 of title 29, Code of Federal Regulations (or  
16      any successor regulations), with respect to any applicable  
17      entity other than a covered plan or a covered service pro-  
18      vider (as defined in section 408(b)(2)(B)(ii) of the Em-  
19      ployee Retirement Income Security Act of 1974, as  
20      amended by subsection (a)).

21      (c) **INDIVIDUAL MARKET COVERAGE.**—Subpart 1 of  
22      part B of title XXVII of the Public Health Service Act  
23      (42 U.S.C. 300gg–41 et seq.) is amended by adding at  
24      the end the following:

1 **“SEC. 2746. DISCLOSURE TO ENROLLEES OF INDIVIDUAL**  
2 **MARKET COVERAGE.**

3 “(a) IN GENERAL.—A health insurance issuer offer-  
4 ing individual health insurance coverage shall make disclo-  
5 sures to enrollees in such coverage, as described in sub-  
6 section (b), and reports to the Secretary, as described in  
7 subsection (c), regarding direct or indirect compensation  
8 provided to an agent or broker associated with enrolling  
9 individuals in such coverage.

10 “(b) DISCLOSURE.—A health insurance issuer de-  
11 scribed in subsection (a) shall disclose to an enrollee the  
12 amount of direct or indirect compensation provided to an  
13 agent or broker for services provided by such agent or  
14 broker associated with plan selection and enrollment. Such  
15 disclosure shall be—

16 “(1) made prior to the individual finalizing plan  
17 selection; and

18 “(2) included on any documentation confirming  
19 the individual’s enrollment.

20 “(c) REPORTING.—A health insurance issuer de-  
21 scribed in subsection (a) shall annually report to the Sec-  
22 retary, prior to the beginning of open enrollment, any di-  
23 rect or indirect compensation provided to an agent or  
24 broker associated with enrolling individuals in such cov-  
25 erage.

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

8       (d) TRANSITION RULE.—No contract executed prior  
9 to the effective date described in subsection (e) by a group  
10 health plan subject to the requirements of section  
11 408(b)(2)(B) of the Employee Retirement Income Secu-  
12 rity Act of 1974 (as amended by subsection (a)) or by  
13 a health insurance issuer subject to the requirements of  
14 section 2746 of the Public Health Service Act (as added  
15 by subsection (c)) shall be subject to the requirements of  
16 such section 408( b)(2)(B) or such section 2746, as appli-  
17 cable.

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

21 **SEC. 309. ENSURING ENROLLEE ACCESS TO COST-SHARING**  
22 **INFORMATION.**

23       (a) IN GENERAL.—Subpart II of part A of title  
24 XXVII of the Public Health Service Act (42 U.S.C.

1 300gg–11 et seq.), as amended by section 306, is further  
2 amended by adding at the end the following:

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

4 “(a) PROVIDER DISCLOSURES.—A provider that is  
5 in-network with respect to a group health plan or a health  
6 insurance issuer offering group or individual health insur-  
7 ance coverage shall provide to an enrollee in the plan or  
8 coverage who submits a request for the information de-  
9 scribed in paragraph (1) or (2), together with accurate  
10 and complete information about the enrollee’s coverage  
11 under the applicable plan or coverage—

12 “(1) as soon as practicable and not later than  
13 2 business days after the enrollee requests such in-  
14 formation, a good faith estimate of the expected en-  
15 rollee cost-sharing for the provision of a particular  
16 health care service (including any service that is rea-  
17 sonably expected to be provided in conjunction with  
18 such specific service); and

19 “(2) as soon as practicable and not later than  
20 2 business days after an enrollee requests such in-  
21 formation, the contact information for any ancillary  
22 providers for a scheduled health care service.

23 “(b) INSURER DISCLOSURES.—A group health plan  
24 or a health insurance issuer offering group or individual  
25 health insurance coverage shall provide an enrollee in the

1 plan or coverage with a good faith estimate of the enroll-  
2 ee’s cost-sharing (including deductibles, copayments, and  
3 coinsurance) for which the enrollee would be responsible  
4 for paying with respect to a specific health care service  
5 (including any service that is reasonably expected to be  
6 provided in conjunction with such specific service), as soon  
7 as practicable and not later than 2 business days after  
8 a request for such information by an enrollee.

9 “(c) ENFORCEMENT.—

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

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

23 (b) EFFECTIVE DATE.—Section 2729G of the Public  
24 Health Service Act, as added by subsection (a), shall apply

1 with respect to plan years beginning on or after the date  
2 that is 18 months after the date of enactment of this Act.

3 **SEC. 310. STRENGTHENING PARITY IN MENTAL HEALTH**  
4 **AND SUBSTANCE USE DISORDER BENEFITS.**

5 Section 2726 of the Public Health Service Act (42  
6 U.S.C. 300gg-26) is amended—

7 (1) in subsection (a), by adding at the end the  
8 following:

9 “(8) COMPLIANCE REQUIREMENTS.—

10 “(A) NONQUANTITATIVE TREATMENT LIM-  
11 ITATION (NQTL) REQUIREMENTS.—In the case  
12 of a group health plan or a health insurance  
13 issuer offering group or individual health insur-  
14 ance coverage that provides both medical and  
15 surgical benefits and mental health or sub-  
16 stance use disorder benefits and that imposes  
17 nonquantitative treatment limitations (referred  
18 to in this section as ‘NQTL’) on mental health  
19 or substance use disorder benefits, the plan or  
20 issuer offering health insurance coverage in  
21 connection with such a plan, shall perform com-  
22 parative analyses of the design and application  
23 of NQTLs in accordance with the following  
24 process, and make available to the applicable  
25 State authority (or, as applicable, to the Sec-

1           retary of Labor with respect to group health  
2           plans or the Secretary of Health and Human  
3           Services with respect to health insurance cov-  
4           erage), upon request within 60 days beginning  
5           6 months after the date of enactment of the  
6           Lower Health Care Costs Act, the following in-  
7           formation:

8                   “(i) The specific plan or coverage  
9                   terms regarding the NQTL, that applies to  
10                  such plan or coverage, and a description of  
11                  all mental health or substance use disorder  
12                  and medical or surgical benefits to which it  
13                  applies in each respective benefits classi-  
14                  fication.

15                  “(ii) The factors used to determine  
16                  that the NQTL will apply to mental health  
17                  or substance use disorder benefits and  
18                  medical or surgical benefits.

19                  “(iii) The evidentiary standards used  
20                  for the factors identified in clause (ii),  
21                  when applicable, provided that every factor  
22                  shall be defined and any other source or  
23                  evidence relied upon to design and apply  
24                  the NQTL to mental health or substance



1 use disorder benefits and medical or sur-  
2 gical benefits.

3 “(iv) The comparative analyses dem-  
4 onstrating that the processes, strategies,  
5 evidentiary standards, and other factors  
6 used to design the NQTL, as written, and  
7 the operation processes and strategies as  
8 written and in operation that are used to  
9 apply the NQTL for mental health or sub-  
10 stance use disorder benefits are com-  
11 parable to, and are applied no more strin-  
12 gently than, the processes, strategies, evi-  
13 dentiary standards, and other factors used  
14 to design the NQTL, as written, and the  
15 operation processes and strategies as writ-  
16 ten and in operation that are used to apply  
17 the NQTL to medical or surgical benefits.

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

24 “(B) SECRETARY REQUEST PROCESS.—

1                   “(i) SUBMISSION UPON REQUEST.—

2                   With respect to group health plans or  
3                   health insurance coverage for which the  
4                   Secretary is enforcing this section in ac-  
5                   cordance with section 2723, the Secretary,  
6                   in consultation with the Secretary of Labor  
7                   and the Secretary of Treasury, shall re-  
8                   quest that a group health plan or a health  
9                   insurance issuer offering group or indi-  
10                  vidual health insurance coverage submit  
11                  the comparative analyses described in sub-  
12                  paragraph (A) for plans that involve poten-  
13                  tial violations of this section concerning  
14                  NQTLs and any other instances in which  
15                  the Secretary determines appropriate. The  
16                  Secretary shall request not fewer than 20  
17                  such analyses per year.

18                  “(ii) ADDITIONAL INFORMATION.—In  
19                  instances in which the Secretary has con-  
20                  cluded that the plan or coverage has not  
21                  submitted sufficient information for the  
22                  Secretary to review the comparative anal-  
23                  yses described in subparagraph (A), as re-  
24                  quested under clause (i), the Secretary  
25                  shall specify to the plan or coverage the in-

1           formation the plan or coverage must sub-  
2           mit to be responsive to the request under  
3           clause (i) for the Secretary to review the  
4           comparative analyses described in subpara-  
5           graph(A) for compliance with this section.  
6           Nothing in this paragraph shall require the  
7           Secretary to conclude that a plan is in  
8           compliance with this section solely based  
9           upon the inspection of the comparative  
10          analyses described in subparagraph (A), as  
11          requested under clause (i).

12           “(iii) REQUIRED ACTION.—In in-  
13          stances in which the Secretary has re-  
14          viewed the comparative analyses described  
15          in subparagraph (A), as requested under  
16          clause (i), and determined that the plan or  
17          coverage is not in compliance with this sec-  
18          tion, the plan or coverage shall specify to  
19          the Secretary the actions the plan or cov-  
20          erage will take to be in compliance with  
21          this section. Documents or communications  
22          produced in connection with the Sec-  
23          retary’s recommendations to the plan or  
24          coverage shall not be subject to disclosure

1                   pursuant to section 552 of title 5, United  
2                   States Code.

3                   “(iv) REPORT.—Not later than 1 year  
4                   after the date of enactment of this para-  
5                   graph, and annually thereafter, the Sec-  
6                   retary shall submit to the Committee on  
7                   Education and Labor of the House of Rep-  
8                   resentatives and the Committee on Health,  
9                   Education, Labor, and Pensions of the  
10                  Senate a report that contains—

11                   “(I) a summary of the compara-  
12                   tive analyses requested under clause  
13                   (i), except that the identity of each  
14                   plan or coverage and any contracted  
15                   entity of a plan or coverage shall be  
16                   redacted;

17                   “(II) the Secretary’s conclusions  
18                   as to whether each plan or coverage  
19                   submitted sufficient information for  
20                   the Secretary to review the compara-  
21                   tive analyses requested under clause  
22                   (i) for compliance with this section;

23                   “(III) for each plan or coverage  
24                   that did submit sufficient information  
25                   for the Secretary to review the com-

1           parative analyses requested under  
2           clause (i), the Secretary’s conclusions  
3           as to whether and why the plan or  
4           coverage is in compliance with the dis-  
5           closure requirements under this sec-  
6           tion;

7                   “(IV) the Secretary’s specifica-  
8                   tions described in clause (ii) for each  
9                   plan or coverage that the Secretary  
10                  determined did not submit sufficient  
11                  information for the Secretary to re-  
12                  view the comparative analyses re-  
13                  quested under clause (i) for compli-  
14                  ance with this section; and

15                   “(V) the Secretary’s specifica-  
16                   tions described in clause (iii) of the  
17                   actions each plan or coverage that the  
18                   Secretary determined is not in compli-  
19                   ance with this section must take to be  
20                   in compliance with this section, in-  
21                   cluding the reason why the Secretary  
22                   determined the plan or coverage is not  
23                   in compliance.

24                   “(C) COMPLIANCE PROGRAM GUIDANCE

25                   DOCUMENT UPDATE PROCESS.—

1           “(i) IN GENERAL.—The Secretary  
2           shall include select instances of noncompli-  
3           ance that the Secretary discovers upon re-  
4           viewing the comparative analyses requested  
5           under subparagraph (B)(i) in the compli-  
6           ance program guidance document de-  
7           scribed in section 2726(a)(6), as it is up-  
8           dated every 2 years, except that all in-  
9           stances shall be deidentified and such in-  
10          stances shall not disclose any protected  
11          health information or individually identifi-  
12          able information.

13           “(ii) GUIDANCE AND REGULATIONS.—  
14          Not later than 18 months after the date of  
15          enactment of this paragraph, the Secretary  
16          shall finalize any draft or interim guidance  
17          and regulations relating to mental health  
18          parity under this section.

19           “(iii) STATE.—The Secretary shall  
20          share information on findings of compli-  
21          ance and noncompliance discovered upon  
22          reviewing the comparative analyses re-  
23          quested under subparagraph (B)(i) shall be  
24          shared with the State where the group  
25          health plan is located or the State where

1 the health insurance issuer is licensed to  
2 do business for coverage offered by a  
3 health insurance issuer in the group mar-  
4 ket, in accordance with section  
5 2726(a)(6)(B)(iii)(II).”.

6 **SEC. 311. TECHNICAL AMENDMENTS.**

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

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

14 (2) in subsection (b)—

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

19 (B) by striking “(as so amended)”.

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

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

1 (2) in subsection (b)—

2 (A) by striking “(as amended by the Pa-  
3 tient Protection and Affordable Care Act)” and  
4 inserting “(including any subsequent amend-  
5 ments to such part)”; and

6 (B) by striking “(as so amended)”.

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

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

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

18 **SEC. 313. GROUP HEALTH PLAN REPORTING REQUIRE-**  
19 **MENTS.**

20 Part C of title XXVII of the Public Health Service  
21 Act (42 U.S.C. 300gg–91 et seq.), as amended by section  
22 303, is further amended by adding at the end the fol-  
23 lowing:



1 **“SEC. 2797. GROUP HEALTH PLAN REPORTING.**

2 “(a) IN GENERAL.—A group health plan or health  
3 insurance issuer offering group or individual health insur-  
4 ance coverage shall submit to the Secretary, not later than  
5 March 1 of each year, the following information with re-  
6 spect to the health plan in the previous plan year:

7 “(1) The beginning and end dates of the plan  
8 year.

9 “(2) The number of enrollees.

10 “(3) Each State in which the plan is offered.

11 “(4) The 50 brand prescription drugs most fre-  
12 quently dispensed by pharmacies for claims paid by  
13 the issuer, and the total number of paid claims for  
14 each such drug.

15 “(5) The 50 most costly prescription drugs with  
16 respect to the plan by total annual spending, and the  
17 annual amount spent by the plan for each such  
18 drug.

19 “(6) The 50 prescription drugs with the great-  
20 est increase in plan expenditures over the plan year  
21 preceding the plan year that is the subject of the re-  
22 port, and, for each such drug, the change in  
23 amounts expended by the plan in each such plan  
24 year.

25 “(7) Total spending on health care services by  
26 such group health plan, broken down by—

- 1                   “(A) the type of costs, including—
- 2                   “ (i) hospital costs;
- 3                   “ (ii) health care provider and clinical
- 4                   service costs;
- 5                   “ (iii) costs for prescription drugs; and
- 6                   “ (iv) other medical costs; and
- 7                   “(B) spending on prescription drugs by—
- 8                   “ (i) the health plan; and
- 9                   “ (ii) the enrollees.
- 10                  “(8) The average monthly premium—
- 11                  “ (A) paid by employers on behalf of enroll-
- 12                  ees; and
- 13                  “ (B) paid by enrollees.
- 14                  “(9) Any impact on premiums by rebates, fees,
- 15                  and any other remuneration paid by drug manufac-
- 16                  turers to the plan or its administrators or service
- 17                  providers, with respect to prescription drugs pre-
- 18                  scribed to enrollees in the plan, including—
- 19                  “ (A) the amounts so paid for each thera-
- 20                  peutic class of drugs; and
- 21                  “ (B) the amounts so paid for each of the
- 22                  25 drugs that yielded the highest amount of re-
- 23                  bates and other remuneration under the plan
- 24                  from drug manufacturers during the plan year.



1 stakeholders, conduct a study on the role of pharmacy  
2 benefit managers.

3 (b) PERMISSIBLE EXAMINATION.—In conducting the  
4 study required under subsection (a), the Comptroller Gen-  
5 eral may examine various qualitative and quantitative as-  
6 pects of the role of pharmacy benefit managers, such as  
7 the following:

8 (1) The role that pharmacy benefit managers  
9 play in the pharmaceutical supply chain.

10 (2) The state of competition among pharmacy  
11 benefit managers, including the market share for the  
12 Nation's largest pharmacy benefit managers.

13 (3) The use of rebates and fees by pharmacy  
14 benefit managers, including—

15 (A) the extent to which rebates are passed  
16 on to health plans and whether such rebates are  
17 passed on to individuals enrolled in such plans;

18 (B) the extent to which rebates are kept by  
19 such pharmacy benefit managers; and

20 (C) the role of any fees charged by such  
21 pharmacy benefit managers.

22 (4) Whether pharmacy benefit managers struc-  
23 ture their formularies in favor of high-rebate pre-  
24 scription drugs over lower-cost, lower-rebate alter-  
25 natives.



1 or more public or private entities to carry out a national,  
2 evidence-based campaign to increase awareness and  
3 knowledge of the safety and effectiveness of vaccines for  
4 the prevention and control of diseases, combat misin-  
5 formation about vaccines, and disseminate scientific and  
6 evidence-based vaccine-related information, with the goal  
7 of increasing rates of vaccination across all ages, as appli-  
8 cable, particularly in communities with low rates of vac-  
9 cination, to reduce and eliminate vaccine-preventable dis-  
10 eases.

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

18 “(c) REQUIREMENTS.—The campaign under this sec-  
19 tion shall—

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

21 “(2) include the development of resources for  
22 communities with low rates of vaccination, including  
23 culturally- and linguistically-appropriate resources,  
24 as applicable;

1           “(3) include the dissemination of vaccine infor-  
2           mation and communication resources to public  
3           health departments, health care providers, and  
4           health care facilities, including such providers and  
5           facilities that provide prenatal and pediatric care;

6           “(4) be complementary to, and coordinated  
7           with, any other Federal, State, local, or Tribal ef-  
8           forts, as appropriate; and

9           “(5) assess the effectiveness of communication  
10          strategies to increase rates of vaccination.

11          “(d) ADDITIONAL ACTIVITIES.—The campaign under  
12          this section may—

13           “(1) include the use of television, radio, the  
14           internet, and other media and telecommunications  
15           technologies;

16           “(2) be focused to address specific needs of  
17           communities and populations with low rates of vac-  
18           cination; and

19           “(3) include the dissemination of scientific and  
20           evidence-based vaccine-related information, such  
21           as—

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

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

7           “(C) information on diseases that may be  
8           prevented by vaccines; and

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

11       “(e) EVALUATION.—The Secretary shall—

12           “(1) establish benchmarks and metrics to quan-  
13           titatively measure and evaluate the awareness cam-  
14           paign under this section;

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

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

22       “(f) SUPPLEMENT NOT SUPPLANT.—Funds appro-  
23       priated under this section shall be used to supplement and  
24       not supplant other Federal, State, and local public funds  
25       provided for activities described in this section.



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

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

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

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

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

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

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

17           “(i) identify communities at high risk of  
18 outbreaks related to vaccine-preventable dis-  
19 eases, including through improved data collec-  
20 tion and analysis;

21           “(ii) pilot innovative approaches to improve  
22 vaccination rates in communities and among  
23 populations with low rates of vaccination;

1           “(iii) reduce barriers to accessing vaccines  
2           and evidence-based information about the  
3           health effects of vaccines;

4           “(iv) partner with community organiza-  
5           tions and health care providers to develop and  
6           deliver evidence-based interventions, including  
7           culturally- and linguistically-appropriate inter-  
8           ventions, to increase vaccination rates;

9           “(v) improve delivery of evidence-based  
10          vaccine-related information to parents and oth-  
11          ers; and

12          “(vi) improve the ability of State, local,  
13          tribal, and territorial public health departments  
14          to engage communities at high risk for out-  
15          breaks related to vaccine-preventable diseases;  
16          and

17          “(F) research related to strategies for improv-  
18          ing awareness of scientific and evidence-based vac-  
19          cine-related information, including for communities  
20          with low rates of vaccination, in order to understand  
21          barriers to vaccination, improve vaccination rates,  
22          and assess the public health outcomes of such strate-  
23          gies.”.

1 (b) SUPPLEMENTAL GRANT FUNDS.—Section  
2 330(d)(1) of the Public Health Service Act (42 U.S.C.  
3 254b) is amended—

4 (1) in subparagraph (F), by striking “and” at  
5 the end;

6 (2) in subparagraph (G), by striking the period  
7 and inserting “; and”; and

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

9 “(H) improving access to recommended  
10 immunizations.”.

11 **SEC. 403. GUIDE ON EVIDENCE-BASED STRATEGIES FOR**  
12 **PUBLIC HEALTH DEPARTMENT OBESITY PRE-**  
13 **VENTION PROGRAMS.**

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

20 (1) develop a guide on evidence-based strategies  
21 for State, territorial, and local health departments to  
22 use to build and maintain effective obesity preven-  
23 tion and reduction programs, and, in consultation  
24 with Indian Tribes and Tribal organizations, a guide  
25 on such evidence-based strategies with respect to In-



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, commu-  
20 nity-based organizations, and others,  
21 as appropriate; and

22 (2) disseminate the guides and current re-  
23 search, evidence-based practices, tools, and edu-  
24 cational materials related to obesity prevention, con-  
25 sistent with the guide, to State, territorial, and local

1 health departments, Indian Tribes, and Tribal orga-  
2 nizations.

3 (b) TECHNICAL ASSISTANCE.—The Secretary, acting  
4 through the Director of the Centers for Disease Control  
5 and Prevention, shall provide technical assistance to State,  
6 territorial, and local health departments, Indian Tribes,  
7 and Tribal organizations to support such health depart-  
8 ments in implementing the guide developed under sub-  
9 section (a)(1).

10 (c) INDIAN TRIBES; TRIBAL ORGANIZATIONS.—The  
11 terms “Indian Tribe” and “Tribal organization” have the  
12 meanings given the terms “Indian tribe” and “tribal orga-  
13 nization”, respectively, in section 4 of the Indian Self-De-  
14 termination and Education Assistance Act (25 U.S.C.  
15 5304).

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

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

20 **“SEC. 330N. EXPANDING CAPACITY FOR HEALTH OUT-  
21 COMES.**

22 “(a) DEFINITIONS.—In this section:

23 “(1) ELIGIBLE ENTITY.—The term ‘eligible en-  
24 tity’ means an entity providing health care services  
25 in rural areas, frontier areas, health professional

1 shortage areas, or medically underserved areas, or to  
2 medically underserved populations or Native Ameri-  
3 cans, including Indian tribes or tribal organizations.

4 “(2) HEALTH PROFESSIONAL SHORTAGE  
5 AREA.—The term ‘health professional shortage area’  
6 means a health professional shortage area des-  
7 ignated under section 332.

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

12 “(4) MEDICALLY UNDERSERVED POPU-  
13 LATION.—The term ‘medically underserved popu-  
14 lation’ has the meaning given the term in section  
15 330(b)(3).

16 “(5) NATIVE AMERICANS.—The term ‘Native  
17 Americans’ has the meaning given such term in sec-  
18 tion 736 and includes Indian tribes and tribal orga-  
19 nizations.

20 “(6) TECHNOLOGY-ENABLED COLLABORATIVE  
21 LEARNING AND CAPACITY BUILDING MODEL.—The  
22 term ‘technology-enabled collaborative learning and  
23 capacity building model’ means a distance health  
24 education model that connects health care profes-  
25 sionals, and particularly specialists, with multiple

1 other health care professionals through simultaneous  
2 interactive videoconferencing for the purpose of fa-  
3 cilitating case-based learning, disseminating best  
4 practices, and evaluating outcomes.

5 “(b) PROGRAM ESTABLISHED.—The Secretary shall,  
6 as appropriate, award grants to evaluate, develop, and, as  
7 appropriate, expand the use of technology-enabled collabo-  
8 rative learning and capacity building models, to increase  
9 access to health care services, such as those to address  
10 chronic diseases and conditions, mental health, substance  
11 use disorders, prenatal and maternal health, pediatric  
12 care, pain management, palliative care, and other specialty  
13 care in rural areas, frontier areas, health professional  
14 shortage areas, or medically underserved areas and for  
15 medically underserved populations or Native Americans,  
16 including Indian Tribes and Tribal organizations.

17 “(c) USE OF FUNDS.—

18 “(1) IN GENERAL.—Grants awarded under sub-  
19 section (b) shall be used for—

20 “(A) the development and acquisition of  
21 instructional programming, and the training of  
22 health care providers and other professionals  
23 that provide or assist in the provision of serv-  
24 ices through such models;



1           “(B) information collection and evaluation  
2           activities to study the impact of such models on  
3           patient outcomes and health care providers, and  
4           to identify best practices for the expansion and  
5           use of such models; or

6           “(C) other activities consistent with achiev-  
7           ing the objectives of the grants awarded under  
8           this section, as determined by the Secretary.

9           “(2) OTHER USES.—In addition to any of the  
10          uses under paragraph (1), grants awarded under  
11          subsection (b) may be used for—

12           “(A) equipment to support the use and ex-  
13           pansion of technology-enabled collaborative  
14           learning and capacity building models, including  
15           for hardware and software that enables distance  
16           learning, health care provider support, and the  
17           secure exchange of electronic health informa-  
18           tion; or

19           “(B) support for health care providers and  
20           other professionals that provide or assist in the  
21           provision of services through such models.

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

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

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

7 “(f) ACCESS TO BROADBAND.—In administering  
8 grants under this section, the Secretary may coordinate  
9 with other agencies to ensure that funding opportunities  
10 are available to support access to reliable, high-speed  
11 internet for grantees.

12 “(g) TECHNICAL ASSISTANCE.—The Secretary shall  
13 provide (either directly through the Department of Health  
14 and Human Services or by contract) technical assistance  
15 to eligible entities, including recipients of grants under  
16 subsection (b), on the development, use, and evaluation  
17 of technology-enabled collaborative learning and capacity  
18 building models in order to expand access to health care  
19 services provided by such entities, including for medically  
20 underserved areas and to medically underserved popu-  
21 lations or Native Americans, including Indian tribes and  
22 Tribal organizations.

23 “(h) RESEARCH AND EVALUATION.—The Secretary,  
24 in consultation with stakeholders with appropriate exper-  
25 tise in such models, shall develop a strategic plan to re-

1 search and evaluate the evidence for such models. The  
2 Secretary shall use such plan to inform the activities car-  
3 ried out under this section.

4 “(i) REPORT BY SECRETARY.—Not later than 4 years  
5 after the date of enactment of this section, the Secretary  
6 shall prepare and submit to the Committee on Health,  
7 Education, Labor, and Pensions of the Senate and the  
8 Committee on Energy and Commerce of the House of  
9 Representatives, and post on the Internet website of the  
10 Department of Health and Human Services, a report in-  
11 cluding, at minimum—

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

15 “(2) an overview of—

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

18 “(B) technical assistance provided under  
19 subsection (g); and

20 “(3) a description of any significant findings or  
21 developments in patient outcomes and health care  
22 providers and best practices for eligible entities ex-  
23 panding, using, or evaluating technology-enabled col-  
24 laborative learning and capacity building models, in-

1 including through the activities described in subsection  
2 (g).

3 “(j) AUTHORIZATION OF APPROPRIATIONS.—There  
4 is authorized to be appropriated to carry out this section,  
5 such sums as may be necessary for each of fiscal years  
6 2020 through 2024.”.

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

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

11 **“SEC. 2822. PUBLIC HEALTH DATA SYSTEM MODERNIZA-**  
12 **TION GRANTS.**

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

16 “(1) award grants to State, local, Tribal, and  
17 territorial public health departments for the expan-  
18 sion and modernization of public health data sys-  
19 tems, to assist public health departments in—

20 “(A) assessing current data infrastructure  
21 capabilities and gaps to improve and increase  
22 consistency in data collection, storage, analysis,  
23 and, as appropriate, to improve dissemination  
24 of public health-related information;

1           “(B) improving secure public health data  
2 collection, transmission, exchange, maintenance,  
3 and analysis;

4           “(C) simplifying and supporting reporting  
5 by health care providers, as applicable, pursu-  
6 ant to State law, including through the use of  
7 health information technology, to State, local,  
8 Tribal, and territorial public health depart-  
9 ments, including public health officials in mul-  
10 tiple jurisdictions within such State, as appro-  
11 priate;

12           “(D) enhancing interoperability of public  
13 health data systems (including systems created  
14 or accessed by public health departments) with  
15 health information technology, including health  
16 information technology certified under section  
17 3001(c)(5);

18           “(E) supporting earlier disease and health  
19 condition detection, such as through near real-  
20 time data monitoring, to support rapid public  
21 health responses; and

22           “(F) supporting activities within the appli-  
23 cable jurisdiction related to the expansion and  
24 modernization of electronic case reporting;

1           “(2) as appropriate, conduct activities related  
2           to the interoperability and improvement of applicable  
3           public health data systems used by the Centers for  
4           Disease Control and Prevention, and, in coordination  
5           with the Office of the National Coordinator for  
6           Health Information Technology, the designation of  
7           data and technology standards for health informa-  
8           tion systems of the public health infrastructure with  
9           deference given to standards published by standards  
10          development organizations and voluntary consensus-  
11          based standards bodies; and

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

19          “(b) REQUIREMENTS.—

20          “(1) IN GENERAL.—The Secretary may not  
21          award a grant under subsection (a)(1) unless the ap-  
22          plicant uses or agrees to use standards recognized  
23          by the National Coordinator for Health Information  
24          Technology pursuant to section 3001(c)(1) or adopt-  
25          ed by the Secretary under section 3004.

1           “(2) WAIVER.—The Secretary may waive the  
2           requirement under paragraph (1) with respect to an  
3           applicant if the Secretary determines that the activi-  
4           ties under subsection (a) cannot otherwise be carried  
5           out within the applicable jurisdiction.

6           “(3) APPLICATION.—A State, local, Tribal, or  
7           territorial health department applying for a grant  
8           under this section shall submit an application to the  
9           Secretary at such time and in such manner as the  
10          Secretary may require. Such application shall in-  
11          clude information describing—

12                   “(A) the activities that will be supported  
13                   by the grant; and

14                   “(B) how the modernization of such public  
15                   health data systems will support or impact the  
16                   public health infrastructure of the health de-  
17                   partment, including a description of remaining  
18                   gaps, if any, and the actions needed to address  
19                   such gaps.

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

23                   “(1) Carrying out activities described in sub-  
24                   section (a)(1) to support public health data systems  
25                   (including electronic case reporting), which may in-

1 include support for, and training of, professionals with  
2 expertise in contributing to and using such systems  
3 (including public health data scientists).

4 “(2) Developing and disseminating information  
5 related to the use and importance of public health  
6 data.

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

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

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

23 “(e) CONSULTATION.—The Secretary, acting through  
24 the Director of the Centers for Disease Control and Pre-  
25 vention, shall consult with State, local, Tribal, and terri-



1 torial health departments, professional medical and public  
2 health associations, associations representing hospitals or  
3 other health care entities, health information technology  
4 experts, and other appropriate entities regarding the plan  
5 and grant program to modernize public health data sys-  
6 tems pursuant to this section. Such activities may include  
7 the provision of technical assistance related to the ex-  
8 change of information by such public health data systems  
9 used by relevant health care and public health entities at  
10 the local, State, Federal, Tribal, and territorial levels.

11 “(f) REPORT TO CONGRESS.—Not later than 1 year  
12 after the date of enactment of this section, the Secretary  
13 shall submit a report to the Committee on Health, Edu-  
14 cation, Labor, and Pensions of the Senate and the Com-  
15 mittee on Energy and Commerce of the House of Rep-  
16 resentatives that includes—

17 “(1) a description of any barriers to—

18 “(A) public health authorities imple-  
19 menting interoperable public health data sys-  
20 tems and electronic case reporting;

21 “(B) the exchange of information pursuant  
22 to electronic case reporting; or

23 “(C) reporting by health care providers  
24 using such public health data systems, as ap-  
25 propriate, and pursuant to State law;

1           “(2) an assessment of the potential public  
2 health impact of implementing electronic case re-  
3 porting and interoperable public health data sys-  
4 tems; and

5           “(3) a description of the activities carried out  
6 pursuant to this section.

7           “(g) ELECTRONIC CASE REPORTING.—In this sec-  
8 tion, the term ‘electronic case reporting’ means the auto-  
9 mated identification, generation, and bilateral exchange of  
10 reports of health events among electronic health record or  
11 health information technology systems and public health  
12 authorities.

13           “(h) AUTHORIZATION OF APPROPRIATIONS.—For the  
14 purpose of carrying out this section, there are authorized  
15 to be appropriated such sums as may be necessary for fis-  
16 cal years 2020 through 2024.”.

17 **SEC. 406. INNOVATION FOR MATERNAL HEALTH.**

18           Title III of the Public Health Service Act is amended  
19 by inserting after section 330N of such Act, as added by  
20 section 404, the following:

21 **“SEC. 330O. INNOVATION FOR MATERNAL HEALTH.**

22           “(a) IN GENERAL.—The Secretary, in consultation  
23 with experts representing a variety of clinical specialties,  
24 State, tribal, or local public health officials, researchers,  
25 epidemiologists, statisticians, and community organiza-

1 tions, shall establish or continue a program to award com-  
2 petitive grants to eligible entities for the purpose of—

3           “(1) identifying, developing, or disseminating  
4           best practices to improve maternal health care qual-  
5           ity and outcomes, eliminate preventable maternal  
6           mortality and severe maternal morbidity, and im-  
7           prove infant health outcomes, which may include—

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

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

23                   “(C) information on addressing deter-  
24                   minants of health that impact maternal health

1 outcomes for women before, during, and after  
2 pregnancy;

3 “(2) collaborating with State maternal mor-  
4 tality review committees to identify issues for the de-  
5 velopment and implementation of evidence-based  
6 practices to improve maternal health outcomes and  
7 reduce preventable maternal mortality and severe  
8 maternal morbidity;

9 “(3) providing technical assistance and sup-  
10 porting the implementation of best practices identi-  
11 fied in paragraph (1) to entities providing health  
12 care services to pregnant and postpartum women;  
13 and

14 “(4) identifying, developing, and evaluating new  
15 models of care that improve maternal and infant  
16 health outcomes, which may include the integration  
17 of community-based services and clinical care.

18 “(b) ELIGIBLE ENTITIES.—To be eligible for a grant  
19 under subsection (a), an entity shall—

20 “(1) submit to the Secretary an application at  
21 such time, in such manner, and containing such in-  
22 formation as the Secretary may require; and

23 “(2) demonstrate in such application that the  
24 entity is capable of carrying out data-driven mater-  
25 nal safety and quality improvement initiatives in the

1 areas of obstetrics and gynecology or maternal  
2 health.

3 “(c) AUTHORIZATION OF APPROPRIATIONS.—To  
4 carry out this section, there is authorized to be appro-  
5 priated such sums as may be necessary for each of fiscal  
6 years 2020 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  
10 the following:

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

12 “(a) GRANT PROGRAM.—The Secretary shall estab-  
13 lish 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  
19 prenatal 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  
2 awarded a grant under this section shall periodically sub-  
3 mit to the Secretary a report on the status of activities  
4 conducted using the grant, including a description of the  
5 impact of 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  
9 (including training related to implicit biases) in the provi-  
10 sion of health care services related to prenatal care, labor  
11 care, birthing, and postpartum care.

12       “(e) AUTHORIZATION OF APPROPRIATIONS.—To  
13 carry out this section, there is authorized to be appro-  
14 priated such sums as may be necessary for each of fiscal  
15 years 2020 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 (re-  
20 ferred to in this section as the “Secretary”) shall, through  
21 a contract with an independent research organization, con-  
22 duct a study and make recommendations for accredited  
23 schools of allopathic medicine, osteopathic medicine, and  
24 nursing, and other health professional training programs  
25 on best practices related to training to reduce and prevent

1 discrimination, including training related to implicit bi-  
2 ases, in the provision of health care services related to pre-  
3 natal 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  
7 end 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 of-  
11 fices and agencies, as appropriate, shall estab-  
12 lish or continue a competitive grant program  
13 for the establishment or support of perinatal  
14 quality collaboratives to improve perinatal care  
15 and 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; ex-  
23 perts; State, local, and, as appropriate,  
24 tribal public health officials; and stake-  
25 holders, including patients and families, to

1 identify, develop, or disseminate best prac-  
2 tices to improve perinatal care and out-  
3 comes; and

4 “(III) employ strategies that provide  
5 opportunities for health care professionals  
6 and clinical teams to collaborate across  
7 health care settings and disciplines, includ-  
8 ing primary care and mental health, as ap-  
9 propriate, to improve maternal and infant  
10 health outcomes, which may include the  
11 use of data to provide timely feedback  
12 across hospital and clinical teams to in-  
13 form responses, and to provide support  
14 and training to hospital and clinical teams  
15 for quality improvement, as appropriate.

16 “(ii) To be eligible for a grant under  
17 clause (i), an entity shall submit to the Sec-  
18 retary an application in such form and manner  
19 and containing such information as the Sec-  
20 retary may require.”.

21 **SEC. 410. INTEGRATED SERVICES FOR PREGNANT AND**  
22 **POSTPARTUM WOMEN.**

23 (a) GRANTS.—Title III of the Public Health Service  
24 Act is amended by inserting after section 3300 of such  
25 Act, 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,  
9 pregnancy-related deaths, and related health disparities  
10 (including such disparities associated with racial and eth-  
11 nic minority populations), and, as appropriate, by address-  
12 ing issues researched under subsection (b)(2) of section  
13 317K.

14 “(b) INTEGRATED SERVICES FOR PREGNANT AND  
15 POSTPARTUM WOMEN.—

16 “(1) ELIGIBILITY.—To be eligible to receive a  
17 grant under subsection (a), a State, Indian Tribe, or  
18 Tribal organization (as such terms are defined in  
19 section 4 of the Indian Self-Determination and Edu-  
20 cation Assistance Act) shall work with relevant  
21 stakeholders that coordinate care (including coordi-  
22 nating resources and referrals for health care and  
23 social services) to develop and carry out the pro-  
24 gram, including—

25 “(A) State, Tribal, and local agencies re-  
26 sponsible for Medicaid, public health, social

1 services, mental health, and substance use dis-  
2 order treatment and services;

3 “(B) health care providers who serve preg-  
4 nant and postpartum women; and

5 “(C) community-based health organiza-  
6 tions and health workers, including providers of  
7 home visiting services and individuals rep-  
8 resenting communities with disproportionately  
9 high rates of maternal mortality and severe ma-  
10 ternal morbidity, and including those rep-  
11 resenting racial and ethnicity minority popu-  
12 lations.

13 “(2) TERMS.—

14 “(A) PERIOD.—A grant awarded under  
15 subsection (a) shall be made for a period of 5  
16 years. Any supplemental award made to a  
17 grantee under subsection (a) may be made for  
18 a period of less than 5 years.

19 “(B) PREFERENCE.—In awarding grants  
20 under subsection (a), the Secretary shall—

21 “(i) give preference to States, Indian  
22 Tribes, and Tribal organizations that have  
23 the highest rates of maternal mortality and  
24 severe maternal morbidity relative to other

1 such States, Indian Tribes, or Tribal orga-  
2 nizations, respectively; and

3 “(ii) shall consider health disparities  
4 related to maternal mortality and severe  
5 maternal morbidity, including such dispari-  
6 ties associated with racial and ethnic mi-  
7 nority populations.

8 “(C) PRIORITY.—In awarding grants  
9 under subsection (a), the Secretary shall give  
10 priority to applications from up to 15 entities  
11 described in subparagraph (B)(i).

12 “(D) EVALUATION.—The Secretary shall  
13 require grantees to evaluate the outcomes of the  
14 programs supported under the grant.

15 “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
16 are authorized to be appropriated to carry out this section  
17 such sums as may be necessary for each of fiscal years  
18 2020 through 2024.”.

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

21 (1) REPORT.—Not later than February 1,  
22 2026, the Secretary of Health and Human Services  
23 shall submit to the Committee on Health, Edu-  
24 cation, Labor, and Pensions of the Senate and the

1 Committee on Energy and Commerce of the House  
2 of Representatives a report that describes—

3 (A) the outcomes of the activities sup-  
4 ported by the grants awarded under the amend-  
5 ments made by this section on maternal and  
6 child health;

7 (B) best practices and models of care used  
8 by recipients of grants under such amendments;  
9 and

10 (C) obstacles identified by recipients of  
11 grants under such amendments, and strategies  
12 used by such recipients to deliver care, improve  
13 maternal and child health, and reduce health  
14 disparities.

15 (2) DISSEMINATION OF BEST PRACTICES.—Not  
16 later than August 1, 2026, the Secretary of Health  
17 and Human Services shall disseminate information  
18 on best practices and models of care used by recipi-  
19 ents of grants under the amendments made by this  
20 section (including best practices and models of care  
21 relating to the reduction of health disparities, includ-  
22 ing such disparities associated with racial and ethnic  
23 minority populations, in rates of maternal mortality  
24 and severe maternal morbidity) to relevant stake-  
25 holders, which may include health providers, medical

1 schools, nursing schools, relevant State, tribal, and  
2 local agencies, and the general public.

3 **SEC. 411. EXTENSION FOR COMMUNITY HEALTH CENTERS,**  
4 **THE NATIONAL HEALTH SERVICE CORPS,**  
5 **AND TEACHING HEALTH CENTERS THAT OP-**  
6 **ERATE GME PROGRAMS.**

7 (a) COMMUNITY HEALTH CENTERS.—Section  
8 10503(b)(1)(F) of the Patient Protection and Affordable  
9 Care Act (42 U.S.C. 254b–2(b)(1)(F)) is amended by  
10 striking “fiscal year 2019” and inserting “each of fiscal  
11 years 2019 through 2024”.

12 (b) NATIONAL HEALTH SERVICE CORPS.—Section  
13 10503(b)(2)(F) of the Patient Protection and Affordable  
14 Care Act (42 U.S.C. 254b–2(b)(2)(F)) is amended by  
15 striking “and 2019” and inserting “through 2024”.

16 (c) TEACHING HEALTH CENTERS THAT OPERATE  
17 GRADUATE MEDICAL EDUCATION PROGRAMS.—Section  
18 340H(g)(1) of the Public Health Service Act (42 U.S.C.  
19 256h(g)(1)) is amended by striking “and 2019” and in-  
20 serting “through 2024”.

21 (d) APPLICATION OF PROVISIONS.—Amounts appro-  
22 priated pursuant to this section for each of fiscal years  
23 2019 through 2024 shall be subject to the requirements  
24 contained in Public Law 115–245 for funds for programs

1 authorized under sections 330 through 340 of the Public  
2 Health Service Act.

3 (e) CONFORMING AMENDMENTS.—Paragraph (4) of  
4 section 3014(h) of title 18, United States Code, as amend-  
5 ed by section 50901 of Public Law 115–123, is amended  
6 by striking “and section 50901(e) of the Advancing  
7 Chronic Care, Extenders, and Social Services Act” and in-  
8 serting “, section 50901(e) of the Advancing Chronic  
9 Care, Extenders, and Social Services Act, and section  
10 411(d) of the Lower Health Care Costs Act”.

11 **SEC. 412. OTHER PROGRAMS.**

12 (a) TYPE I.—Section 330B(b)(2)(D) of the Public  
13 Health Service Act (42 U.S.C. 254e–2(b)(2)(D)) is  
14 amended by striking “and 2019” and inserting “through  
15 2024”.

16 (b) INDIANS.—Subparagraph (D) of section  
17 330C(c)(2) of the Public Health Service Act (42 U.S.C.  
18 254e–3(c)(2)(D)) is amended by striking “and 2019” and  
19 inserting “through 2024”.

20 **SEC. 413. NATIVE AMERICAN SUICIDE PREVENTION.**

21 Section 520E(b) of the Public Health Service Act (42  
22 U.S.C. 290bb–36(b) is amended by inserting after para-  
23 graph (3) the following:

24 “(4) CONSULTATION.—A State applying for a  
25 grant or cooperative agreement under this section

1 shall, in the development and implementation of a  
2 statewide early intervention strategy, consult or con-  
3 fer with entities described in paragraph (1)(C) in  
4 such State.”.

5 **SEC. 414. MINIMUM AGE OF SALE OF TOBACCO PRODUCTS.**

6 (a) IN GENERAL.—Section 906(d) of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)) is  
8 amended—

9 (1) in paragraph (3)(A)(ii), by striking “18  
10 years” and inserting “21 years”; and

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

12 “(5) MINIMUM AGE OF SALE.—It shall be un-  
13 lawful for any retailer to sell a tobacco product to  
14 any person younger than 21 years of age.”.

15 (b) REGULATIONS.—Not later than 180 days after  
16 the date of enactment of this Act, the Secretary of Health  
17 and Human Services (referred to in this section as the  
18 “Secretary”) shall publish in the Federal Register a final  
19 rule to update the regulations issued under chapter IX of  
20 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387  
21 et seq.) as appropriate, only to carry out the amendments  
22 made by subsection (a), including updating the relevant  
23 age verification requirements under part 1140 of title 21,  
24 Code of Federal Regulations to require age verification for  
25 individuals under the age of 30. Such final rule shall—

1           (1) take full effect not later than 90 days after  
2           the date on which such final rule is published; and

3           (2) be deemed to be in compliance with all ap-  
4           plicable provisions of chapter 5 of title 5, United  
5           States Code and all other provisions of law relating  
6           to rulemaking procedures.

7           (c) NOTIFICATION.—Not later than 90 days after the  
8           date of enactment of this Act, the Secretary shall provide  
9           written notification to the Committee on Health, Edu-  
10          cation, Labor, and Pensions of the Senate and the Com-  
11          mittee on Energy and Commerce of the House of Rep-  
12          resentatives regarding the progress of the Department of  
13          Health and Human Services towards promulgating the  
14          final rule under subsection (b). If, 180 days after the date  
15          of enactment of this Act, such rule has not been promul-  
16          gated in accordance with subsection (b), the Secretary  
17          shall provide a written notification and a justification for  
18          the delay in rulemaking to such committees.

19          (d) PENALTIES FOR VIOLATIONS.—

20                 (1) IN GENERAL.—Section 103(q)(2) of the  
21                 Family Smoking Prevention and Tobacco Control  
22                 Act (Public Law 111–31) is amended—

23                         (A) in subparagraph (A), in the matter  
24                         preceding clause (i), by inserting “section  
25                         906(d)(5) or of” after “violations of”; and



1 (B) in subparagraph (C), by inserting  
2 “section 906(d)(5) or of” after “a retailer of”.

3 (2) REPEATED VIOLATIONS.—Section 303(f)(8)  
4 of the Federal Food, Drug, and Cosmetic Act (21  
5 U.S.C. 333(f)(8)) is amended by inserting “section  
6 906(d)(5) or of” after “repeated violations of”.

7 (3) MISBRANDED PRODUCTS.—Section  
8 903(a)(7)(B) of the Federal Food, Drug, and Cos-  
9 metic Act (21 U.S.C. 387c) is amended by inserting  
10 “section 906(d)(5) or of” after “violation of”.

11 **SEC. 415. SALE OF TOBACCO PRODUCTS TO INDIVIDUALS**  
12 **UNDER THE AGE OF 21.**

13 (a) IN GENERAL.—Section 1926 of the Public Health  
14 Service Act (42 U.S.C. 300x–26) is amended—

15 (1) in the heading—

16 (A) by striking “**STATE LAW REGARD-**  
17 **ING**”; and

18 (B) by striking “**18**” and inserting “**21**”;

19 (2) by striking subsections (a) and (d);

20 (3) by redesignating subsections (b) and (c) as  
21 subsections (a) and (b), respectively;

22 (4) by amending subsection (a), as so redesign-  
23 nated, to read as follows:

24 “(a) IN GENERAL.—A funding agreement for a grant  
25 under section 1921 is that the State involved will—



1 (D) by striking “subsections (a) and (b)”  
2 and inserting “subsection (a)”;

3 (E) by striking “equal to—” and inserting  
4 “up to 10 percent of the amount determined  
5 under section 1933 for the State for the appli-  
6 cable fiscal year.”; and

7 (F) by adding at the end the following:

8 “(2) LIMITATION.—

9 “(A) IN GENERAL.—A State shall not have  
10 funds withheld pursuant to paragraph (1) if  
11 such State for which the Secretary has made a  
12 determination of noncompliance under such  
13 paragraph—

14 “(i) certifies to the Secretary by May  
15 1 of the fiscal year for which the funds are  
16 appropriated, consistent with subparagraph  
17 (B), that the State will commit additional  
18 State funds, in accordance with paragraph  
19 (1), to ensure that retailers do not sell to-  
20 bacco products to individuals under 21  
21 years of age;

22 “(ii) agrees to comply with a nego-  
23 tiated agreement for a corrective action  
24 plan that is approved by the Secretary and

1 carried out in accordance with guidelines  
2 issued by the Secretary; or

3 “(iii) is a territory that receives less  
4 than \$1,000,000 for a fiscal year under  
5 section 1921.

6 “(B) CERTIFICATION.—

7 “(i) IN GENERAL.—The amount of  
8 funds to be committed by a State pursuant  
9 to subparagraph (A)(i) shall be equal to 1  
10 percent of such State’s substance abuse al-  
11 location determined under section 1933 for  
12 each percentage point by which the State  
13 misses the retailer compliance rate goal es-  
14 tablished by the Secretary.

15 “(ii) STATE EXPENDITURES.—For a  
16 fiscal year in which a State commits funds  
17 as described in clause (i), such State shall  
18 maintain State expenditures for tobacco  
19 prevention programs and for compliance  
20 activities at a level that is not less than the  
21 level of such expenditures maintained by  
22 the State for the preceding fiscal year, plus  
23 the additional funds for tobacco compliance  
24 activities required under clause (i). The  
25 State shall submit a report to the Sec-

1           retary on all State obligations of funds for  
2           such fiscal year and all State expenditures  
3           for the preceding fiscal year for tobacco  
4           prevention and compliance activities by  
5           program activity by July 31 of such fiscal  
6           year.

7                   “(iii) DISCRETION.—The Secretary  
8           shall exercise discretion in enforcing the  
9           timing of the State obligation of the addi-  
10          tional funds required by the certification  
11          described in subparagraph (A)(i) as late as  
12          July 31 of such fiscal year.

13                   “(C) FAILURE TO CERTIFY.—If a State  
14          described in subparagraph (A) fails to certify to  
15          the Secretary pursuant to subparagraph (A)(i)  
16          or enter into, or comply with, a negotiated  
17          agreement under subparagraph (A)(ii), the Sec-  
18          retary may take action pursuant to paragraph  
19          (1).”; and

20          (6) by adding at the end the following:

21                   “(c) IMPLEMENTATION OF REPORTING REQUIRE-  
22          MENTS.—

23                   “(1) TRANSITION PERIOD.—The Secretary  
24          shall—

1           “(A) not withhold amounts under sub-  
2           section (b) for the 3-year period immediately  
3           following the date of enactment of the Lower  
4           Health Care Costs Act; and

5           “(B) use discretion in exercising its au-  
6           thority under subsection (b) during the 2-year  
7           period immediately following the 3-year period  
8           described in subparagraph (A), to allow for a  
9           transition period for implementation of the re-  
10          porting requirements under subsection (a)(2).

11          “(2) REGULATIONS OR GUIDANCE.—Not later  
12          than 180 days after the date of enactment of the  
13          Lower Health Care Costs Act the Secretary shall  
14          update regulations under part 96 of title 45, Code  
15          of Federal Regulations or guidance on the retailer  
16          compliance rate goal under subsection (b), the use of  
17          funds provided under section 1921 for purposes of  
18          meeting the requirements of this section, and report-  
19          ing requirements under subsection (a)(2).

20          “(3) COORDINATION.—The Secretary shall en-  
21          sure the Assistant Secretary for Mental Health and  
22          Substance Use coordinates, as appropriate, with the  
23          Commissioner of Food and Drugs in providing tech-  
24          nical assistance under this section to States, related  
25          to ensuring retailers do not sell tobacco products to

1 individuals under the age of 21, that is consistent  
2 with applicable regulations issued by the Food and  
3 Drug Administration.

4 “(d) TRANSITIONAL GRANTS.—

5 “(1) IN GENERAL.—The Secretary shall award  
6 grants under this subsection to each State that re-  
7 ceives funding under section 1921 to ensure compli-  
8 ance of each such State with this section.

9 “(2) USE OF FUNDS.—A State receiving a  
10 grant under this subsection—

11 “(A) shall use amounts received under  
12 such grant for activities to plan for or ensure  
13 compliance in the States that ensure compliance  
14 in the State with subsection (a); and

15 “(B) in the case of a State for which the  
16 Secretary has made a determination under sub-  
17 section (b) that the State is prepared to meet,  
18 or has met, the requirements of subsection (a),  
19 may use such funds for tobacco cessation activi-  
20 ties, strategies to prevent the use of tobacco  
21 products by individuals under the age of 21, or  
22 allowable uses under section 1921.

23 “(3) SUPPLEMENT NOT SUPPLANT.—Grants  
24 under this subsection shall be used to supplement  
25 and not supplant other Federal, State, and local

1 public funds provided for activities under this sec-  
2 tion.

3 “(4) AUTHORIZATION OF APPROPRIATIONS.—  
4 To carry out this subsection, there are authorized to  
5 be appropriated \$18,580,790 for each of fiscal years  
6 2020 through 2024.

7 “(5) SUNSET.—This subsection shall have no  
8 force or effect after September 30, 2024.

9 “(e) TECHNICAL ASSISTANCE.—The Secretary shall  
10 provide technical assistance to States related to the activi-  
11 ties required under this section.”.

12 (b) REPORT TO CONGRESS.—Not later than 3 years  
13 after the date of enactment of this Act, the Secretary shall  
14 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 report  
17 on the status of implementing the requirements of section  
18 1926 of the Public Health Service Act (42 U.S.C. 300x–  
19 26), as amended by subsection (a), and a description of  
20 any technical assistance provided under subsection (e) of  
21 such section, including the number of meetings held and  
22 requested related to technical assistance.

23 (c) CONFORMING AMENDMENT.—Section 212 of divi-  
24 sion D of the Consolidated Appropriations Act, 2010  
25 (Public Law 111–117) is repealed.



1 **TITLE V—IMPROVING THE EX-**  
2 **CHANGE OF HEALTH INFOR-**  
3 **MATION**

4 **SEC. 501. REQUIREMENT TO PROVIDE HEALTH CLAIMS,**  
5 **NETWORK, AND COST INFORMATION.**

6 (a) IN GENERAL.—Part A of title XXVII of the Pub-  
7 lic Health Service Act (42 U.S.C. 300gg et seq.) is amend-  
8 ed by inserting after section 2715A the following:

9 **“SEC. 2715B. REQUIREMENT TO PROVIDE HEALTH CLAIMS,**  
10 **NETWORK, AND COST INFORMATION.**

11 “(a) IN GENERAL.—A group health plan or a health  
12 insurance issuer offering group or individual health insur-  
13 ance coverage shall make available for access, exchange,  
14 and use without special effort, through application pro-  
15 gramming interfaces (or successor technology or stand-  
16 ards), the information described in subsection (b), in the  
17 manner described in subsection (b) and otherwise con-  
18 sistent with this section.

19 “(b) INFORMATION.—The following information is re-  
20 quired to be made available, as the Secretary may specify:

21 “(1) Historical claims, provider encounter, and  
22 payment data for each enrollee, which shall—

23 “(A) include adjudicated medical and pre-  
24 scription drug claims and equivalent encoun-

1           ters, including all data elements contained in  
2           such transactions—

3                   “(i) that were adjudicated by the  
4                   group health plan or health insurance  
5                   issuer during the previous 5 years or the  
6                   enrollee’s entire period of enrollment in the  
7                   applicable plan or coverage if such period  
8                   is less than the previous 5 years;

9                   “(ii) that involve benefits managed by  
10                  any third party, such as a pharmacy bene-  
11                  fits manager or radiology benefits manager  
12                  that manages benefits or adjudicates  
13                  claims on behalf of the plan or coverage;  
14                  and

15                  “(iii) from any other health plan or  
16                  health insurance coverage offered by the  
17                  same insurance issuer, in which the same  
18                  enrollee was enrolled during the previous 5  
19                  years; and

20                  “(B) be available to an enrollee or former  
21                  enrollee, the enrollee’s providers, and any third-  
22                  party applications or services authorized by the  
23                  enrollee—

24                   “(i) through the application program-  
25                   ming interfaces (or successor technology or

1 standards) as required by this paragraph,  
2 in a single, longitudinal format that is easy  
3 to understand, secure, and that may up-  
4 date automatically;

5 “(ii) as soon as practicable, and in no  
6 case later than the period of time deter-  
7 mined by the Secretary, after the claim is  
8 adjudicated or the data is received by the  
9 health plan or health insurance issuer; and

10 “(iii) to the enrollee, former enrollee,  
11 and any providers or third-party applica-  
12 tions or services authorized by the enrollee,  
13 for 5 years after the end date of the enroll-  
14 ee’s enrollment in the plan or in any cov-  
15 erage offered by the health insurance  
16 issuer.

17 “(2) Identifying directory information for all in-  
18 network providers, including facilities and practi-  
19 tioners, that participate in the plan or coverage,  
20 which shall—

21 “(A) include—

22 “(i) the national provider identifier  
23 for in-network facilities and practitioners;  
24 and

1                   “(ii) the name, address, phone num-  
2                   ber, and specialty for each such facility  
3                   and practitioner, based on the most recent  
4                   interaction between the plan or coverage  
5                   and that facility or practitioner;

6                   “(B) be capable of returning the informa-  
7                   tion necessary to establish a list of participating  
8                   in-network facilities and practitioners, in a  
9                   given specialty or at a particular facility type,  
10                  within a specified geographic radius; and

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

14                  “(3) Estimated enrollee out-of-pocket costs, in-  
15                  cluding costs expected to be incurred through a de-  
16                  ductible, co-payment, coinsurance, or other form of  
17                  cost-sharing, for—

18                  “(A) a designated set of common services  
19                  or episodes of care, to be established by the  
20                  Secretary through rulemaking, including, at a  
21                  minimum—

22                  “(i) in the case of services provided by  
23                  a hospital, the 100 most common diag-  
24                  nosis-related groups, as used in the Medi-  
25                  care Inpatient Prospective Patient System

1 (or successor episode-based reimbursement  
2 methodology) at that hospital, based on  
3 claims data adjudicated by the group  
4 health plan or health insurance issuer;

5 “(ii) in the case of services provided  
6 in an out-patient setting, including radi-  
7 ology, lab tests, and out-patient surgical  
8 procedures, any service rendered by the fa-  
9 cility or practitioner, and reimbursed by  
10 the health plan or health insurance issuer;  
11 and

12 “(iii) in the case of post-acute care,  
13 including home health providers, skilled  
14 nursing facilities, inpatient rehabilitation  
15 facilities, and long-term care hospitals, the  
16 patient out-of-pocket costs for an episode  
17 of care, as the Secretary may determine,  
18 which permits users to reasonably compare  
19 costs across different facility and service  
20 types; and

21 “(B) all prescription drugs currently in-  
22 cluded on any tier of the formulary of the plan  
23 or coverage.

24 “(c) AVAILABILITY AND ACCESS.—Subject to all ap-  
25 plicable Federal and State privacy, security, and breach

1 notification laws, the application programming interfaces,  
2 including all data required to be made available through  
3 such interfaces, shall—

4 “(1) be made available by the applicable group  
5 health plan or health insurance issuer, at no charge,  
6 to—

7 “(A) enrollees and prospective enrollees in  
8 the group health plan or health insurance cov-  
9 erage;

10 “(B) third parties authorized by the en-  
11 rollee;

12 “(C) facilities and practitioners who are  
13 under contract with the plan or coverage; and

14 “(D) business associates of such facilities  
15 and practitioners, as defined in section 160.103  
16 of title 45, Code of Federal Regulations (or any  
17 successor regulations);

18 “(2) be available to enrollees in the group  
19 health plan or health insurance coverage, and to  
20 third-party applications or services facilitating such  
21 access by enrollees, during the enrollment process  
22 and for a minimum of 5 years after the end date of  
23 the enrollee’s enrollment in the plan or in any cov-  
24 erage offered by the health insurance issuer;

1           “(3) permit persistent access by third party ap-  
2           plications or services authorized by the enrollee, for  
3           a reasonable period of time, consistent with the re-  
4           quirements of the HIPAA Security rule (part 160 of  
5           title 45 Code of Federal Regulations and subparts A  
6           and C of part 164 of such title);

7           “(4) employ the applicable content, vocabulary,  
8           and technical standards, as determined by the Sec-  
9           retary pursuant to title XXX; and

10           “(5) employ security and authentication stand-  
11           ards, as the Secretary determines appropriate.

12           “(d) RULE OF CONSTRUCTION REGARDING PRI-  
13           VACY.—Nothing in this section shall be construed to alter  
14           existing obligations of a covered entity or business asso-  
15           ciate under the privacy, security, and breach notification  
16           rules promulgated under section 264(c) of the Health In-  
17           surance Portability and Accountability Act or section  
18           13402 of the HITECH Act, or to alter the Secretary’s  
19           existing authority to modify such rules, under part 2 of  
20           title 42, Code of Federal Regulations (or successor regula-  
21           tions), under section 444 of the General Education Provi-  
22           sions Act (20 U.S.C. 1232g) (commonly referred to as the  
23           ‘Family Educational Rights and Privacy Act of 1974’),  
24           under the amendments made by the Genetic Information  
25           Nondiscrimination Act, or under State privacy law.”.

1 (b) EFFECTIVE DATE.—Section 2715B of the Public  
2 Health Service Act, as added by subsection (a), shall take  
3 effect 18 months after the date of enactment of this Act.

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

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

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

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

20 “(1) mitigate fines under section 13410;

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

23 “(3) mitigate the remedies that would otherwise  
24 be agreed to in any agreement with respect to re-  
25 solving potential violations of the HIPAA Security



1 rule (part 160 of title 45 Code of Federal Regula-  
2 tions and subparts A and C of part 164 of such  
3 title) between the covered entity or business asso-  
4 ciate and the Department of Health and Human  
5 Services.

6 “(b) DEFINITION AND MISCELLANEOUS PROVI-  
7 SIONS.—

8 “(1) RECOGNIZED SECURITY PRACTICES.—The  
9 term ‘recognized security practices’ means the stand-  
10 ards, guidelines, best practices, methodologies, pro-  
11 cedures, and processes developed under section  
12 2(c)(15) of the National Institute of Standards and  
13 Technology Act, the approaches promulgated under  
14 section 405(d) of the Cybersecurity Act of 2015, and  
15 other programs and processes that address cyberse-  
16 curity and that are developed, recognized, or promul-  
17 gated through regulations under other statutory au-  
18 thorities. Such practices shall be determined by the  
19 covered entity or business associate.

20 “(2) LIMITATION.—Nothing in this section  
21 shall be construed as providing the Secretary author-  
22 ity to increase fines under section 13410, or the  
23 length, extent or quantity of audits under section  
24 13411, due to a lack of compliance with the recog-  
25 nized security practices.

1           “(3) NO LIABILITY FOR NONPARTICIPATION.—  
2           Subject to paragraph (4), nothing in this section  
3           shall be construed to subject a covered entity or  
4           business associate to liability for electing not to en-  
5           gage in the recognized security practices defined by  
6           this section.

7           “(4) RULE OF CONSTRUCTION.—Nothing in  
8           this section shall be construed to limit the Sec-  
9           retary’s authority to enforce the HIPAA Security  
10          rule (part 160 of title 45 Code of Federal Regula-  
11          tions and subparts A and C of part 164 of such  
12          title), or to supersede or conflict with an entity or  
13          business associate’s obligations under the HIPAA  
14          Security rule.”.

15 **SEC. 503. GAO STUDY ON THE PRIVACY AND SECURITY**  
16                   **RISKS OF ELECTRONIC TRANSMISSION OF IN-**  
17                   **DIVIDUALLY IDENTIFIABLE HEALTH INFOR-**  
18                   **MATION TO AND FROM ENTITIES NOT COV-**  
19                   **ERED BY THE HEALTH INSURANCE PORT-**  
20                   **ABILITY AND ACCOUNTABILITY ACT.**

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

24                  (1) describe the roles of Federal agencies and  
25          the private sector with respect to protecting the pri-

1 vacy and security of individually identifiable health  
2 information transmitted electronically to and from  
3 entities not covered by the regulations promulgated  
4 under section 264(c) of the Health Insurance Port-  
5 ability and Accountability Act of 1996 (42 U.S.C.  
6 1320d–2 note);

7 (2) identify recent developments regarding the  
8 use of application programming interfaces to access  
9 individually identifiable health information, and im-  
10 plications for the privacy and security of such infor-  
11 mation;

12 (3) identify practices in the private sector, such  
13 as terms and conditions for use, relating to the pri-  
14 vacy, disclosure, and secondary uses of individually  
15 identifiable health information transmitted electroni-  
16 cally to or from entities, selected by an individual,  
17 that are not subject to the regulations promulgated  
18 under section 264(c) of the Health Insurance Port-  
19 ability and Accountability Act of 1996; and

20 (4) identify steps the public and private sectors  
21 can take to improve the private and secure access to  
22 and availability of individually identifiable health in-  
23 formation.

24 (b) REPORT.—Not later than 1 year after the date  
25 of enactment of this Act, the Comptroller General of the

1 United States shall submit to Congress a report con-  
2 cerning the findings of the study conducted under sub-  
3 section (a).

4 **SEC. 504. TECHNICAL CORRECTIONS.**

5 (a) IN GENERAL.—Section 3022(b) of the Public  
6 Health Service Act (42 U.S.C. 300jj–52(b)) is amended  
7 by adding at the end the following new paragraph:

8 “(4) APPLICATION OF AUTHORITIES UNDER IN-  
9 SPECTOR GENERAL ACT OF 1978.—In carrying out  
10 this subsection, the Inspector General shall have the  
11 same authorities as provided under section 6 of the  
12 Inspector General Act of 1978 (5 U.S.C. App.).”.

13 (b) EFFECTIVE DATE.—The amendment made by  
14 subsection (a) shall take effect as if included in the enact-  
15 ment of the 21st Century Cures Act (Public Law 114–  
16 255).

17 **SEC. 505. PUBLIC MEETING.**

18 (a) IN GENERAL.—Not later than 180 days after the  
19 date of enactment of this Act, the Secretary of Health and  
20 Human Services shall convene a public meeting for pur-  
21 poses of discussing and providing input on patient-match-  
22 ing metrics for the purpose of enabling interoperability  
23 and the exchange of health information across health care  
24 organizations.

1 (b) EXPERTS.—The public meeting under this section  
2 may include—

3 (1) representatives of relevant Federal agencies  
4 (including representatives from the Office of the Na-  
5 tional Coordinator for Health Information Tech-  
6 nology);

7 (2) State, local, Tribal, and territorial public  
8 health officials;

9 (3) stakeholders with expertise in health infor-  
10 mation exchange;

11 (4) stakeholders with expertise in capabilities  
12 relevant to patient matching, such as experts in  
13 informatics and data analytics;

14 (5) stakeholders affected by record-matching  
15 (including patients, hospitals, health systems, pay-  
16 ers, health information exchanges, and prescription  
17 drug monitoring programs); and

18 (6) other representatives, as the Secretary de-  
19 termines appropriate.

20 (c) TOPICS.—Such public meeting shall include a dis-  
21 cussion of—

22 (1) standards and processes for assessing the  
23 accuracy of patient-matching algorithms;

- 1           (2) performance metrics for health care pro-  
2           viders purchasing patient-matching technology and  
3           algorithm developers;
- 4           (3) the development of benchmarks for the ac-  
5           curacy of patient-matching algorithms;
- 6           (4) considerations for State, local, Tribal, and  
7           territorial capabilities and infrastructure related to  
8           data exchange, interoperability, and matching pa-  
9           tient records;
- 10          (5) opportunities for the incorporation of inno-  
11          vative technologies to improve patient matching; and
- 12          (6) privacy and security protections.