

Calendar No. 133

116TH CONGRESS
1ST SESSION

S. 1895

To lower health care costs.

IN THE SENATE OF THE UNITED STATES

JUNE 19, 2019

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

JULY 8, 2019

Reported by Mr. ALEXANDER, with an amendment

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

A BILL

To lower health care costs.

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

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

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

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

See: 1. Short title; table of contents.

TITLE I—ENDING SURPRISE MEDICAL BILLS

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

TITLE II—REDUCING THE PRICES OF PRESCRIPTION DRUGS

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

TITLE III—IMPROVING TRANSPARENCY IN HEALTH CARE

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

TITLE IV—IMPROVING PUBLIC HEALTH

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

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

TITLE V—IMPROVING THE EXCHANGE OF HEALTH INFORMATION

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

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

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

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

7 (1) in paragraph (1)—

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

11 (B) in subparagraph (C)—

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

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

(2) in paragraph (2)(B)—

(A) in clause (i)—

(i) by inserting “or freestanding emergency room” after “hospital”; and

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

(B) in clause (ii), by inserting “or emergency room” after “hospital”.

SEC. 102. PROTECTION AGAINST SURPRISE BILLS.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

consent to receiving services from such practitioner or facility;

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

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

“(C) has acknowledged that the out-of-network treatment may not be covered or may be covered at an out-of-network cost-sharing amount, requiring higher cost-sharing obligations of the enrollee than if the service were provided at an in-network facility; and has assumed, in writing, full responsibility of out-of-pocket costs associated with services furnished after the enrollee has been stabilized, from the out-of-network practitioner or facility, as applicable.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 ~~“(3) ENFORCEMENT.—~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 “(b) MEDIAN IN-NETWORK RATE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 “(c) MEDIAN IN-NETWORK RATE.—

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

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

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

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

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

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

10 “(e) ENFORCEMENT.—

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

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

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

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

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

15 **SEC. 106. REPORT.**

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

21 (1) conduct a study on—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 “(2) PUBLICATION OF INFORMATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

“(ii) a full list of the articles used as components of such drug;

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

“(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

“(v) such samples of such drug and of the articles used as components thereof as the Secretary may require;

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

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

“(viii) the patent number and expiration date, of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug; and that—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 “~~(IV)~~ section 505A;

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

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

6 (1) IN GENERAL.—

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

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

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

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

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

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

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

4 (1) in paragraph (1)—

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

7 (B) in subparagraph (E)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ing standards that are more onerous or rigorous than the standards applicable to the listed drug, reference product, or petitioner's version of the same drug.

~~“(gg) The petitioner's record of submitting petitions to the Food and Drug Administration that have been determined by the Secretary to have been submitted with the primary purpose of delay.~~

~~“(hh) Other relevant and appropriate factors, which the Secretary shall describe in guidance.~~

~~“(III) GUIDANCE.—The Secretary may issue or update guidance, as appropriate, to describe factors the Secretary considers in accordance with subelause (H).”;~~

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

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

Federal Trade Commission any petition or supplement to a petition that the Secretary determines was submitted with the primary purpose of delaying approval of an application. Such procedures shall include notification to the petitioner and an opportunity for judicial review after the issuance of an order by the Federal Trade Commission.”;

(D) by striking subparagraph (F);

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

(F) in subparagraph (H), as so redesignated, by striking “submission of this petition” and inserting “submission of this document”;

(2) in paragraph (2)—

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

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

“(A) IN GENERAL.—A person shall submit a petition to the Secretary under paragraph (1) before filing a civil action in which the person seeks to set aside, delay, rescind, withdraw, or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 ~~(3)~~ in paragraph (4)—

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

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

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

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

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

19 “(D) DEEMED LICENSES.—

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

2009 shall not be treated as having been first licensed under subsection (a) for purposes of subparagraphs (A) and (B).

“(ii) LIMITATION ON EXCLUSIVITY.—Subparagraph (C) shall apply to any reference product, without regard to whether—

“(I) such product was first licensed under subsection (a); or

“(II) the approved application for such product was deemed to be a license for a biological product as described in clause (i).

“(iii) APPLICABILITY.—Any unexpired period of exclusivity under section 527 or section 505A(c)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act with respect to a biological product shall continue to apply to such biological product after an approved application for the biological product is deemed to be a license for the biological product as described in clause (i).”.

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

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

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

8 “(aa) The date”; and

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

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

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

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

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

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

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

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

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

17 “(a) INTERNET WEBSITE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 “(1) a product”;

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

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

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

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

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

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

21 (A) in subsection (c)(3)(E)—

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

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

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

10 (B) in subsection (j)(5)(F)—

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

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

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

(D) in subsection (s), in the matter preceding paragraph (1), by striking “active ingredient (including any ester or salt of the active ingredient)” and inserting “active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))”; and

(E) in subsection (u)(1), in the matter preceding subparagraph (A)—

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

(ii) by striking “same active ingredient” and inserting “same active moiety”;

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

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

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

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

(3) in section 524(a)(4)(C) (21 U.S.C. 360n(a)(4)(C)), by striking “active ingredient (including any ester or salt of the active ingredient)” and inserting “active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))”;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 “(iii) section 527(a); or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 ~~“(2) CHANGES TO LABELING.—After consid-~~
4 ~~ering all responses from the holder of an approved~~
5 ~~application under paragraph (1) or (2) of subsection~~
6 ~~(c), 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 ~~fecte’d.’~~

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

23 ~~“(h) LIMITATIONS; GENERIC DRUGS.—~~

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

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

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

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

20 ~~“(j) RULES OF CONSTRUCTION.—~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(iii) service codes; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 ~~“(b) REQUIREMENTS.—~~

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

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

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

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

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

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

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

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

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

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

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

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

24 “(D) be available to—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~“(3) CONSULTATION.—~~

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

to in this section as the ‘Committee’), consisting of 11 members, to advise the Secretary, the contracting entity, and Congress on the establishment, operations, and use of the database established under this section.

“(B) MEMBERSHIP.—

“(i) APPOINTMENT.—In accordance with clause (ii), the Secretary, in consultation with the Secretary of Health and Human Services, and the Comptroller General of the United States shall, not later than 1 year after the date of enactment of the Lower Health Care Costs Act, appoint members to the Committee who have distinguished themselves in the fields of health services research, health economics, health informatics, or the governance of State all-payer claims databases, or who represent organizations likely to submit data to or use the database, including patients, employers, or employee organizations that sponsor group health plans, health care providers, health insurance issuers, and third-party administrators of group health plans. Such members shall

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

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

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

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

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

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

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

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

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

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

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

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

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

24 “(dd) 1 patient advocate;
25 and

1 ~~“(cc) 2 additional members.~~

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

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

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

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

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

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

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

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

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

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

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

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

22 “(c) CONTRACT REQUIREMENTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the entity so designated by the Secretary. The Secretary shall include enforcement terms in any contract with an organization chosen under this section, to ensure the timely transfer of all data to a new entity in the event of contract termination.

“(d) RECEIVING HEALTH INFORMATION.—

“(1) REQUIREMENTS.—

“(A) IN GENERAL.—An applicable self-insured group health plan shall, through its health insurance issuer, third-party administrator, pharmacy benefit manager, or other entity designated by the group health plan, electronically submit all claims data with respect to the plan, pursuant to subparagraph (B).

“(B) SCOPE OF INFORMATION AND FORMAT OF SUBMISSION.—The entity awarded the contract under subsection (a), in consultation with the Committee described in subsection (b)(3), and pursuant to the privacy and security requirements of subsection (b)(2), shall—

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

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

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

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

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

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

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

tion process described in clause (i) retain the minimum necessary information to perform such a process, and adhere to effective security and encryption practices in data storage and transmission;

“(iii) store claims and other data collected under this subsection only in de-identified form, in accordance with section 164.514(a) of title 45, Code of Federal Regulations (or any successor regulations); and

“(iv) ensure that data is encrypted, in accordance with the regulations promulgated under section 264(e) of the Health Insurance Portability and Accountability Act of 1996.

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

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

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

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

15 “(4) RECEIVING OTHER INFORMATION.—

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

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

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

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

7 ~~“(e) USES OF INFORMATION.—~~

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

14 ~~“(2) AUTHORIZATION OF USERS.—~~

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

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

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

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

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

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

16 “(C) REQUIREMENTS.—

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

1 formation and proprietary financial infor-
2 mation.

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

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

1 “(iv) ~~NON-CUSTOMIZED REPORTS.—~~

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

7 “(f) ~~FUNDING.—~~

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

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

19 “(g) ~~ANNUAL REPORT.—~~

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

lish online for access by the general public; a report
containing a description of—

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

“(B) limitations in the data set;

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

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

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

“(h) GRANTS TO STATES.—

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

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

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

10 ~~“(i) EXEMPTION FROM PUBLIC DISCLOSURE.—~~

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

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

21 ~~“(j) DEFINITIONS.—~~

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

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

3 ~~“(2) PROPRIETARY FINANCIAL INFORMATION.—~~

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

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

17 (b) GAO REPORT.—

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

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

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

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

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

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

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

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

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

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

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

6 **“(a) NETWORK STATUS OF PROVIDERS.—**

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

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

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

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

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

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

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

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

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

3 “(b) ~~COST-SHARING LIMITATIONS.~~—

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

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

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

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

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

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

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

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

25 “(d) ENFORCEMENT.—

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

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

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

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

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

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

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

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

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

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

23 (a) IN GENERAL.—

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

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

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

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

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

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

23 “(c) EFFECT OF VIOLATION.—

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

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

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

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

11 and

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

16 “(2) CIVIL MONETARY PENALTIES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 curred during the reporting pe-
2 riod; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 entity providing pharmacy benefits management
2 services; and

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

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

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

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

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

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

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

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

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

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

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

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

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

15 ~~“(e) ENFORCEMENT.—~~

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

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

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

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

20 “(f) DEFINITIONS.—In this section—

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

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

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

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

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

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

16 (A) involve one or more—

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

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

24 (iii) surgical services;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(aa) the name of the covered plan;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 “(c) ENFORCEMENT.—

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

1 ~~“(2) PROCEDURE.—~~The provisions of section
 2 1128A of the Social Security Act, other than sub-
 3 sections (a) and (b) and the first sentence of sub-
 4 section (c)(1) of such section, shall apply to civil
 5 money penalties under this subsection in the same
 6 manner as such provisions apply to a penalty or pro-
 7 ceeding under section 1128A of the Social Security
 8 Act.”.

9 ~~(b) EFFECTIVE DATE.—~~Section 2729G of the Public
 10 Health Service Act, as added by subsection (a), shall apply
 11 with respect to plan years beginning on or after January
 12 1, 2021.

13 **SEC. 310. STRENGTHENING PARITY IN MENTAL HEALTH**
 14 **AND SUBSTANCE USE DISORDER BENEFITS.**

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

17 (1) in subsection (a), by adding at the end the
 18 following:

19 ~~“(8) COMPLIANCE REQUIREMENTS.—~~

20 ~~“(A) NONQUANTITATIVE TREATMENT LIM-~~
 21 ~~ITATION (NQTL) REQUIREMENTS.—~~In the case
 22 of a group health plan or a health insurance
 23 issuer offering group or individual health insur-
 24 ance coverage that provides both medical and
 25 surgical benefits and mental health or sub-

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

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

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

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

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

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

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

23 “(B) SECRETARY REQUEST PROCESS.—

24 “(i) SUBMISSION UPON COMPLAINT.—

25 The Secretary shall request that a group

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 (2) in subsection (b)—

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

22 (B) by striking “(as so amended)”.

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

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

5 ~~(2) in subsection (b)—~~

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

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

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

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

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

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

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

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

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

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

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

1 priate public health and medical experts, including the Na-
 2 tional Academy of Medicine and medical and public health
 3 associations and nonprofit organizations, in the develop-
 4 ment, implementation, and evaluation of the evidence-
 5 based public awareness campaign.

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

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

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

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

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

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

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

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

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

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

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

13 “(B) information on vaccinations for indi-
14 viduals and communities, including individuals
15 for whom vaccines are not recommended by the
16 Advisory Committee for Immunization Prac-
17 tices, and the effects of low vaccination rates
18 within a community on such individuals;

19 “(C) information on diseases that may be
20 prevented by vaccines; and

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

23 “(e) EVALUATION.—The Secretary shall—

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

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

6 “(3) prepare and submit to the Committee on
7 Health, Education, Labor, and Pensions of the Sen-
8 ate and the Committee on Energy and Commerce of
9 the House of Representatives an evaluation of the
10 awareness campaign under this section.

11 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
12 are authorized to be appropriated to carry out this section
13 and section 317(k) such sums as may be necessary for
14 fiscal years 2020 through 2024.”.

15 **SEC. 402. GRANTS TO ADDRESS VACCINE-PREVENTABLE**
16 **DISEASES.**

17 Section 317(k)(1) of the Public Health Service Act
18 (~~42 U.S.C. 247b(k)(1)~~) is amended—

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

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

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

1 “(E) planning, implementation, and evaluation
2 of activities to address vaccine-preventable diseases;
3 including activities to—

4 “(i) identify communities at high risk of
5 outbreaks related to vaccine-preventable dis-
6 eases, including through improved data collec-
7 tion and analysis;

8 “(ii) pilot innovative approaches to improve
9 vaccination rates in communities and among
10 populations with low rates of vaccination;

11 “(iii) reduce barriers to accessing vaccines
12 and evidence-based information about the
13 health effects of vaccines;

14 “(iv) partner with community organiza-
15 tions and health care providers to develop and
16 deliver evidence-based interventions, including
17 culturally and linguistically appropriate inter-
18 ventions, to increase vaccination rates;

19 “(v) improve delivery of evidence-based
20 vaccine-related information to parents and oth-
21 ers; and

22 “(vi) improve the ability of State, local,
23 tribal, and territorial public health departments
24 to engage communities at high risk for out-

1 breaks related to vaccine-preventable diseases;
 2 and
 3 “(F) research related to strategies for improv-
 4 ing awareness of scientific and evidence-based vac-
 5 cine-related information, including for communities
 6 with low rates of vaccination, in order to understand
 7 barriers to vaccination, improve vaccination rates,
 8 and assess the public health outcomes of such strate-
 9 gies.”.

10 **SEC. 403. GUIDE ON EVIDENCE-BASED STRATEGIES FOR**
 11 **PUBLIC HEALTH DEPARTMENT OBESITY PRE-**
 12 **VENTION PROGRAMS.**

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

19 (1) develop a guide on evidence-based strategies
 20 for State, territorial, and local health departments to
 21 use to build and maintain effective obesity preven-
 22 tion and reduction programs; and, in consultation
 23 with stakeholders that have expertise in Tribal
 24 health, a guide on such evidence-based strategies
 25 with respect to Indian Tribes and Tribal organiza-

1 tions for such Indian Tribes and Tribal organiza-
2 tions to use for such purpose, both of which guides
3 shall—

4 (A) describe an integrated program struc-
5 ture for implementing interventions proven to
6 be effective in preventing and reducing the inci-
7 dence of obesity; and

8 (B) recommend—

9 (i) optimal resources, including staff-
10 ing and infrastructure, for promoting nu-
11 trition and obesity prevention and reduc-
12 tion; and

13 (ii) strategies for effective obesity pre-
14 vention programs for State and local
15 health departments, Indian Tribes, and
16 Tribal organizations, including strategies
17 related to—

18 (I) the application of evidence-
19 based and evidence-informed practices
20 to prevent and reduce obesity rates;

21 (II) the development, implemen-
22 tation, and evaluation of obesity pre-
23 vention and reduction strategies for
24 specific communities and populations;

1 (III) demonstrated knowledge of
 2 obesity prevention practices that re-
 3 duce associated preventable diseases;
 4 health conditions; death; and health
 5 care costs;

6 (IV) best practices for the coordi-
 7 nation of efforts to prevent and re-
 8 duce obesity and related chronic dis-
 9 eases;

10 (V) addressing the underlying
 11 risk factors and social determinants of
 12 health that impact obesity rates; and

13 (VI) interdisciplinary coordina-
 14 tion between relevant public health of-
 15 ficials specializing in fields such as
 16 nutrition; physical activity; epidemi-
 17 ology; communications; and policy im-
 18 plementation; and collaboration be-
 19 tween public health officials and com-
 20 munity-based organizations; and

21 (2) disseminate the guides and current re-
 22 search; evidence-based practices; tools; and edu-
 23 cational materials related to obesity prevention; con-
 24 sistent with the guide; to State and local health de-
 25 partments; Indian Tribes; and Tribal organizations.

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

7 (c) INDIAN TRIBES; TRIBAL ORGANIZATIONS.—The
 8 terms “Indian Tribe” and “Tribal organization” have the
 9 meanings given the terms “Indian tribe” and “tribal orga-
 10 nization”, respectively, in section 4 of the Indian Self-De-
 11 termination and Education Assistance Act (25 U.S.C.
 12 5304).

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

14 Title III of the Public Health Service Act is amended
 15 by inserting after section 330M (42 U.S.C. 254e–19) the
 16 following:

17 **“SEC. 330N. EXPANDING CAPACITY FOR HEALTH OUT-**
 18 **COMES.**

19 “(a) DEFINITIONS.—In this section:

20 “(1) ELIGIBLE ENTITY.—The term ‘eligible en-
 21 tity’ means an entity providing health care services
 22 in rural areas, frontier areas, health professional
 23 shortage areas, or medically underserved areas, or to
 24 medically underserved populations or Native Ameri-
 25 cans, including Indian tribes or tribal organizations.

1 “(2) HEALTH PROFESSIONAL SHORTAGE
2 AREA.—The term ‘health professional shortage area’
3 means a health professional shortage area des-
4 ignated under section 332.

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

9 “(4) MEDICALLY UNDERSERVED POPU-
10 LATION.—The term ‘medically underserved popu-
11 lation’ has the meaning given the term in section
12 330(b)(3).

13 “(5) NATIVE AMERICANS.—The term ‘Native
14 Americans’ has the meaning given such term in sec-
15 tion 736 and includes Indian tribes and tribal orga-
16 nizations.

17 “(6) TECHNOLOGY-ENABLED COLLABORATIVE
18 LEARNING AND CAPACITY BUILDING MODEL.—The
19 term ‘technology-enabled collaborative learning and
20 capacity building model’ means a distance health
21 education model that connects specialists with mul-
22 tiple other health care professionals through simulta-
23 neous interactive videoconferencing for the purpose
24 of facilitating case-based learning; disseminating
25 best practices; and evaluating outcomes.

1 “(b) PROGRAM ESTABLISHED.—The Secretary shall,
 2 as appropriate, award grants to evaluate, develop, and, as
 3 appropriate, expand the use of technology-enabled collabo-
 4 rative learning and capacity building models, to increase
 5 access to health care services, such as those to address
 6 chronic diseases and conditions, mental health, substance
 7 use disorders, prenatal and maternal health, pediatric
 8 care, pain management, palliative care, and other specialty
 9 care in medically underserved areas and for medically un-
 10 derserved populations.

11 “(c) USE OF FUNDS.—

12 “(1) IN GENERAL.—Grants awarded under sub-
 13 section (b) shall be used for—

14 “(A) the development and acquisition of
 15 instructional programming; and the training of
 16 health care providers and other professionals
 17 that provide or assist in the provision of serv-
 18 ices through such models;

19 “(B) information collection and evaluation
 20 activities to study the impact of such models on
 21 patient outcomes and health care providers, and
 22 to identify best practices for the expansion and
 23 use of such models; or

1 “(C) other activities consistent with achiev-
 2 ing the objectives of the grants awarded under
 3 this section, as determined by the Secretary.

4 “(2) OTHER USES.—In addition to any of the
 5 uses under paragraph (1), grants awarded under
 6 subsection (b) may be used for—

7 “(A) equipment to support the use and ex-
 8 pansion of technology-enabled collaborative
 9 learning and capacity building models, including
 10 for hardware and software that enables distance
 11 learning, health care provider support, and the
 12 secure exchange of electronic health informa-
 13 tion; or

14 “(B) support for health care providers and
 15 other professionals that provide or assist in the
 16 provision of services through such models.

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

19 “(e) APPLICATION.—An eligible entity that seeks to
 20 receive a grant under subsection (b) shall submit to the
 21 Secretary an application, at such time, in such manner,
 22 and containing such information as the Secretary may re-
 23 quire. Such application criteria shall include an assess-
 24 ment of the effect of technology-enabled collaborative

1 learning and capacity building models on patient outcomes
 2 and health care providers.

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

13 ~~“(g) REPORT BY SECRETARY.—~~Not later than 4
 14 years after the date of enactment of this section, the Sec-
 15 retary shall prepare and submit to the Committee on
 16 Health, Education, Labor, and Pensions of the Senate and
 17 the Committee on Energy and Commerce of the House
 18 of Representatives, and post on the internet website of the
 19 Department of Health and Human Services, a report in-
 20 cluding, at minimum—

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

24 ~~“(2) an overview of—~~

3 ~~“(B) technical assistance provided under~~
4 ~~subsection (f); and~~

“(3) a description of any significant findings or developments in patient outcomes and health care providers and best practices for eligible entities expanding, using, or evaluating technology-enabled collaborative learning and capacity building models.

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

14 SEC. 405. PUBLIC HEALTH DATA SYSTEM MODERNIZATION.

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

18 “SEC. 2822. PUBLIC HEALTH DATA SYSTEM MODERNIZA-
19 TION GRANTS.

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

23 “(1) award grants to State, local, Tribal, and
24 territorial public health departments for the expan-

1 sion and modernization of public health data sys-
2 tems, to assist public health departments in—

3 “(A) assessing current data infrastructure
4 capabilities and gaps to improve and increase
5 consistency in data collection, storage, analysis,
6 and, as appropriate, to improve dissemination
7 of public health-related information;

8 “(B) improving secure public health data
9 collection, transmission, exchange, maintenance,
10 and analysis;

11 “(C) simplifying and supporting reporting
12 by health care providers, as applicable, pursu-
13 ant to State law, including through the use of
14 health information technology, to State, local,
15 Tribal, and territorial public health depart-
16 ments, including public health officials in mul-
17 tiple jurisdictions within such State, as appro-
18 priate;

19 “(D) enhancing interoperability of public
20 health data systems (including systems created
21 or accessed by public health departments) with
22 health information technology, including cer-
23 tified health information technology;

24 “(E) supporting earlier disease and health
25 condition detection, such as through near real-

1 time data monitoring; to support rapid public
2 health responses; and

3 ~~“(F) supporting activities within the appli-~~
4 ~~cable jurisdiction related to the expansion and~~
5 ~~modernization of electronic case reporting;~~

6 ~~“(2) as appropriate, conduct activities related~~
7 ~~to the interoperability and improvement of applicable~~
8 ~~public health data systems used by the Centers for~~
9 ~~Disease Control and Prevention; and, in coordination~~
10 ~~with the Office of the National Coordinator for~~
11 ~~Health Information Technology, the designation of~~
12 ~~data and technology standards for health informa-~~
13 ~~tion systems of the public health infrastructure with~~
14 ~~deference given to standards published by standards~~
15 ~~development organizations and voluntary consensus-~~
16 ~~based standards bodies; and~~

17 ~~“(3) develop and utilize public-private partner-~~
18 ~~ships for technical assistance and related implemen-~~
19 ~~tation support for State, local, Tribal, and territorial~~
20 ~~public health departments, and the Centers for Dis-~~
21 ~~ease Control and Prevention, on the expansion and~~
22 ~~modernization of electronic case reporting and public~~
23 ~~health data systems, as applicable.~~

24 ~~“(b) REQUIREMENTS.—~~

1 “(1) IN GENERAL.—The Secretary may not
 2 award a grant under subsection (a)(1) unless the ap-
 3 plicant supports standards endorsed by the National
 4 Coordinator for Health Information Technology pur-
 5 suant to section 3001(e)(1) or adopted by the Sec-
 6 retary under section 3004.

7 “(2) WAIVER.—The Secretary may waive the
 8 requirement under paragraph (1) with respect to an
 9 applicant if the Secretary determines that the activi-
 10 ties under subsection (a) cannot otherwise be carried
 11 out within the applicable jurisdiction.

12 “(3) APPLICATION.—A State, local, Tribal, or
 13 territorial health department applying for a grant
 14 under this section shall submit an application to the
 15 Secretary at such time and in such manner as the
 16 Secretary may require. Such application shall in-
 17 clude information describing—

18 “(A) the activities that will be supported
 19 by the grant; and

20 “(B) how the modernization of such public
 21 health data systems will support or impact the
 22 public health infrastructure of the health de-
 23 partment, including a description of remaining
 24 gaps, if any, and the actions needed to address
 25 such gaps.

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

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

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

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

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

1 ~~“(2) carry out the activities described in this~~
2 ~~section to support the improvement of State, local,~~
3 ~~Tribal, and territorial public health data systems.~~

4 ~~“(e) CONSULTATION.—The Secretary, acting through~~
5 ~~the Director of the Centers for Disease Control and Pre-~~
6 ~~vention, shall consult with State, local, Tribal, and terri-~~
7 ~~torial health departments, professional medical and public~~
8 ~~health associations, associations representing hospitals or~~
9 ~~other health care entities, health information technology~~
10 ~~experts, and other appropriate entities regarding the plan~~
11 ~~and grant program to modernize public health data sys-~~
12 ~~tems pursuant to this section. Such activities may include~~
13 ~~the provision of technical assistance related to the ex-~~
14 ~~change of information by such public health data systems~~
15 ~~used by relevant health care and public health entities at~~
16 ~~the local, State, Federal, Tribal, and territorial levels.~~

17 ~~“(f) REPORT TO CONGRESS.—Not later than 1 year~~
18 ~~after the date of enactment of this section, the Secretary~~
19 ~~shall submit a report to the Committee on Health, Edu-~~
20 ~~cation, Labor, and Pensions of the Senate and the Com-~~
21 ~~mittee on Energy and Commerce of the House of Rep-~~
22 ~~resentatives that includes—~~

23 ~~“(1) a description of any barriers to—~~

1 “(A) public health authorities imple-
 2 menting electronic case reporting and interoper-
 3 able public health data systems; or

4 “(B) the exchange of information pursuant
 5 to electronic case reporting;

6 “(2) an assessment of the potential public
 7 health impact of implementing electronic case re-
 8 porting and interoperable public health data sys-
 9 tems; and

10 “(3) a description of the activities carried out
 11 pursuant to this section.

12 “(g) **ELECTRONIC CASE REPORTING.**—In this sec-
 13 tion, the term ‘electronic case reporting’ means the auto-
 14 mated identification, generation, and bilateral exchange of
 15 reports of health events among electronic health record or
 16 health information technology systems and public health
 17 authorities.

18 “(h) **AUTHORIZATION OF APPROPRIATIONS.**—For the
 19 purpose of carrying out this section, there are authorized
 20 to be appropriated such sums as may be necessary for fis-
 21 cal years 2020 through 2024.”.

22 **SEC. 406. INNOVATION FOR MATERNAL HEALTH.**

23 (a) **IN GENERAL.**—The Secretary of Health and
 24 Human Services (referred to in this section as the “Sec-
 25 retary”), in consultation with experts representing a vari-

1 ety of clinical specialties, State, tribal, or local public
2 health officials, researchers, epidemiologists, statisticians,
3 and community organizations, shall establish a program
4 to award competitive grants to eligible entities for the pur-
5 pose of—

6 (1) identifying, developing, or disseminating
7 best practices to improve maternal health care qual-
8 ity and outcomes, eliminate preventable maternal
9 mortality and severe maternal morbidity, and im-
10 prove infant health outcomes, which may include—

11 (A) information on evidence-based prae-
12 tices to improve the quality and safety of ma-
13 ternal health care in hospitals and other health
14 care settings of a State or health care system,
15 including by addressing topics commonly associ-
16 ated with health complications or risks related
17 to prenatal care, labor care, birthing, and post-
18 partum care;

19 (B) best practices for improving maternal
20 health care based on data findings and reviews
21 conducted by a State maternal mortality review
22 committee that address topics of relevance to
23 common complications or health risks related to
24 prenatal care, labor care, birthing, and postpar-
25 tum care; and

1 (C) information on addressing deter-
2 minants of health that impact maternal health
3 outcomes for women before, during, and after
4 pregnancy;

5 (2) collaborating with State maternal mortality
6 review committees to identify issues for the develop-
7 ment and implementation of evidence-based practices
8 to improve maternal health outcomes and reduce
9 preventable maternal mortality and severe maternal
10 morbidity;

11 (3) providing technical assistance and sup-
12 porting the implementation of best practices identi-
13 fied in paragraph (1) to entities providing health
14 care services to pregnant and postpartum women;
15 and

16 (4) identifying, developing, and evaluating new
17 models of care that improve maternal and infant
18 health outcomes, which may include the integration
19 of community-based services and clinical care.

20 (b) ELIGIBLE ENTITIES.—To be eligible for a grant
21 under subsection (a), an entity shall—

22 (1) submit to the Secretary an application at
23 such time, in such manner, and containing such in-
24 formation as the Secretary may require; and

1 (2) demonstrate in such application that the en-
 2 tity has a demonstrated expertise in data-driven ma-
 3 ternal safety and quality improvement initiatives in
 4 the areas of obstetrics and gynecology or maternal
 5 health.

6 (c) AUTHORIZATION OF APPROPRIATIONS.—To carry
 7 out this section, there is authorized to be appropriated
 8 such sums as may be necessary for each of fiscal years
 9 2020 through 2024.

10 **SEC. 407. TRAINING FOR HEALTH CARE PROVIDERS.**

11 Title VII of the Public Health Service Act is amended
 12 by striking section 763 (42 U.S.C. 294p) and inserting
 13 the following:

14 **“SEC. 763. TRAINING FOR HEALTH CARE PROVIDERS.**

15 “(a) GRANT PROGRAM.—The Secretary shall estab-
 16 lish a program to award grants to accredited schools of
 17 allopathic medicine, osteopathic medicine, and nursing,
 18 and other health professional training programs for the
 19 training of health care professionals to reduce and prevent
 20 discrimination (including training related to implicit bi-
 21 ases) in the provision of health care services related to
 22 prenatal care, labor care, birthing, and postpartum care.

23 “(b) ELIGIBILITY.—To be eligible for a grant under
 24 subsection (a), an entity described in such subsection shall
 25 submit to the Secretary an application at such time, in

1 such manner, and containing such information as the Sec-
 2 retary may require.

3 “(c) REPORTING REQUIREMENT.—Each entity
 4 awarded a grant under this section shall periodically sub-
 5 mit to the Secretary a report on the status of activities
 6 conducted using the grant, including a description of the
 7 impact of such training on patient outcomes, as applicable.

8 “(d) BEST PRACTICES.—The Secretary may identify
 9 and disseminate best practices for the training of health
 10 care professionals to reduce and prevent discrimination
 11 (including training related to implicit biases) in the provi-
 12 sion of health care services related to prenatal care, labor
 13 care, birthing, and postpartum care.

14 “(e) AUTHORIZATION OF APPROPRIATIONS.—To
 15 carry out this section, there is authorized to be appro-
 16 priated such sums as may be necessary for each of fiscal
 17 years 2020 through 2024.”.

18 **SEC. 408. STUDY ON TRAINING TO REDUCE AND PREVENT**
 19 **DISCRIMINATION.**

20 Not later than 2 years after date of enactment of this
 21 Act, the Secretary of Health and Human Services (re-
 22 ferred to in this section as the “Secretary”) shall, through
 23 a contract with an independent research organization,
 24 study and make recommendations for accredited schools
 25 of allopathic medicine, osteopathic medicine, and nursing;

1 and other health professional training programs on best
 2 practices related to training to reduce and prevent dis-
 3 crimination, including training related to implicit biases,
 4 in the provision of health care services related to prenatal
 5 care, labor care, birthing, and postpartum care.

6 **SEC. 409. PERINATAL QUALITY COLLABORATIVES.**

7 Section 317K(a)(2) of the Public Health Service Act
 8 (42 U.S.C. 247b–12(a)(2)) is amended by adding at the
 9 end the following:

10 “(E)(i) The Secretary, acting through the
 11 Director of the Centers for Disease Control and
 12 Prevention and in coordination with other of-
 13 fices and agencies, as appropriate, shall estab-
 14 lish or continue a competitive grant program
 15 for the establishment or support of perinatal
 16 quality collaboratives to improve perinatal care
 17 and perinatal health outcomes for pregnant and
 18 postpartum women and their infants. A State
 19 or Indian Tribe may use funds received through
 20 such grant to—

21 “(I) support the use of evidence-based
 22 or evidence-informed practices to improve
 23 outcomes for maternal and infant health;

24 “(II) work with clinical teams; ex-
 25 perts; State, local, and, as appropriate,

1 tribal public health officials; and stake-
2 holders, including patients and families, to
3 identify, develop, or disseminate best prac-
4 tices to improve perinatal care and out-
5 comes; and

6 “(III) employ strategies that provide
7 opportunities for health care professionals
8 and clinical teams to collaborate across
9 health care settings and disciplines, includ-
10 ing primary care and mental health, as ap-
11 propriate, to improve maternal and infant
12 health outcomes, which may include the
13 use of data to provide timely feedback
14 across hospital and clinical teams to in-
15 form responses, and to provide support
16 and training to hospital and clinical teams
17 for quality improvement, as appropriate.

18 “(ii) To be eligible for a grant under
19 clause (i), an entity shall submit to the Sec-
20 retary an application in such form and manner
21 and containing such information as the Sec-
22 retary may require.”

1 **SEC. 410. INTEGRATED SERVICES FOR PREGNANT AND**
 2 **POSTPARTUM WOMEN.**

3 (a) GRANTS.—Title III of the Public Health Service
 4 Act is amended by inserting after section 330N of such
 5 Act, as added by section 404, the following:

6 **“SEC. 330O. INTEGRATED SERVICES FOR PREGNANT AND**
 7 **POSTPARTUM WOMEN.**

8 “(a) IN GENERAL.—The Secretary may award grants
 9 for the purpose of establishing or operating evidence-based
 10 or innovative, evidence-informed programs to deliver inte-
 11 grated health care services to pregnant and postpartum
 12 women to optimize the health of women and their infants,
 13 including to reduce adverse maternal health outcomes,
 14 pregnancy-related deaths, and related health disparities
 15 (including such disparities associated with racial and eth-
 16 nic minority populations), and as appropriate, by address-
 17 ing issues researched under subsection (b)(2) of section
 18 317K.

19 “(b) INTEGRATED SERVICES FOR PREGNANT AND
 20 POSTPARTUM WOMEN.—

21 “(1) ELIGIBILITY.—To be eligible to receive a
 22 grant under subsection (a), a State or Indian Tribe
 23 (as defined in section 4 of the Indian Self-Deter-
 24 mination and Education Assistance Act) shall work
 25 with relevant stakeholders that coordinate care (in-
 26 cluding coordinating resources and referrals for

1 health care and social services) to develop and carry
 2 out the program, including—

3 “(A) State, tribal, and local agencies re-
 4 sponsible for Medicaid, public health, social
 5 services, mental health, and substance use dis-
 6 order treatment and services;

7 “(B) health care providers who serve preg-
 8 nant women; and

9 “(C) community-based health organiza-
 10 tions and health workers, including providers of
 11 home visiting services and individuals rep-
 12 resenting communities with disproportionately
 13 high rates of maternal mortality and severe ma-
 14 ternal morbidity, and including those rep-
 15 resenting racial and ethnicity minority popu-
 16 lations.

17 “(2) TERMS.—

18 “(A) LIMITATION.—The Secretary may
 19 award a grant under subsection (a) to up to 10
 20 States.

21 “(B) PERIOD.—A grant awarded under
 22 subsection (a) shall be made for a period of 5
 23 years.

24 “(C) PRIORITIZATION.—In awarding
 25 grants under subsection (a), the Secretary shall

1 prioritize applications from States or Indian
 2 Tribes with the highest rates of maternal mor-
 3 tality and severe maternal morbidity; and shall
 4 consider health disparities related to maternal
 5 mortality and severe maternal morbidity, in-
 6 cluding such disparities associated with racial
 7 and ethnic minority populations.

8 “(D) EVALUATION.—The Secretary shall
 9 require grantees to evaluate the outcomes of the
 10 programs supported under the grant.

11 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
 12 are authorized to be appropriated to carry out this section
 13 such sums as may be necessary for each of fiscal years
 14 2020 through 2024.”.

15 (b) REPORT ON GRANT OUTCOMES AND DISSEMINA-
 16 TION OF BEST PRACTICES.—

17 (1) REPORT.—Not later than April 1, 2025, the
 18 Secretary of Health and Human Services shall sub-
 19 mit to the Committee on Health, Education, Labor,
 20 and Pensions of the Senate and the Committee on
 21 Energy and Commerce of the House of Representa-
 22 tives a report that describes—

23 (A) the outcomes of the activities sup-
 24 ported by the grants awarded under the amend-

1 ments made by this section on maternal and
2 child health;

3 (B) best practices and models of care used
4 by recipients of grants under such amendments;
5 and

6 (C) obstacles identified by recipients of
7 grants under such amendments, and strategies
8 used by such recipients to deliver care, improve
9 maternal and child health, and reduce health
10 disparities.

11 (2) DISSEMINATION OF BEST PRACTICES.—Not
12 later than October 1, 2025, the Secretary of Health
13 and Human Services shall disseminate information
14 on best practices and models of care used by recipi-
15 ents of grants under the amendments made by this
16 section (including best practices and models of care
17 relating to the reduction of health disparities, includ-
18 ing such disparities associated with racial and ethnic
19 minority populations, in rates of maternal mortality
20 and severe maternal morbidity) to relevant stake-
21 holders, which may include health providers, medical
22 schools, nursing schools, relevant State, tribal, and
23 local agencies, and the general public.

1 **SEC. 411. EXTENSION FOR COMMUNITY HEALTH CENTERS,**
 2 **THE NATIONAL HEALTH SERVICE CORPS,**
 3 **AND TEACHING HEALTH CENTERS THAT OP-**
 4 **ERATE GME PROGRAMS.**

5 (a) **COMMUNITY HEALTH CENTERS FUNDING.**—Sec-
 6 tion 10503(b)(1)(F) of the Patient Protection and Afford-
 7 able Care Act (42 U.S.C. 254b–2(b)(1)(F)) is amended
 8 by striking “fiscal year 2019” and inserting “each of fiscal
 9 years 2019 through 2024”.

10 (b) **NATIONAL HEALTH SERVICE CORPS.**—Section
 11 10503(b)(2)(F) of the Patient Protection and Affordable
 12 Care Act (42 U.S.C. 254b–2(b)(2)(F)) is amended by
 13 striking “and 2019” and inserting “through 2024”.

14 (c) **TEACHING HEALTH CENTERS THAT OPERATE**
 15 **GRADUATE MEDICAL EDUCATION PROGRAMS.**—Section
 16 340H(g)(1) of the Public Health Service Act (42 U.S.C.
 17 256h(g)(1)) is amended by striking “and 2019” and in-
 18 serting “through 2024”.

19 (d) **APPLICATION OF PROVISIONS.**—Amounts appro-
 20 priated pursuant to this section for each of fiscal years
 21 2019 through 2024 shall be subject to the requirements
 22 contained in Public Law 115–245 for funds for programs
 23 authorized under sections 330 through 340 of the Public
 24 Health Service Act.

25 (e) **CONFORMING AMENDMENTS.**—Paragraph (4) of
 26 section 3014(h) of title 18, United States Code, as amend-

1 ed by section 50901 of Public Law 115–123, is amended
 2 by striking “and section 50901(e) of the Advancing
 3 Chronic Care, Extenders, and Social Services Act” and in-
 4 serting “, section 50901(e) of the Advancing Chronic
 5 Care, Extenders, and Social Services Act, and section
 6 411(d) of the Lower Health Care Costs Act”.

7 **SEC. 412. OTHER PROGRAMS.**

8 (a) TYPE I.—Section 330B(b)(2)(D) of the Public
 9 Health Service Act (42 U.S.C. 254c–2(b)(2)(D)) is
 10 amended by striking “and 2019” and inserting “through
 11 2024”.

12 (b) INDIANS.—Subparagraph (D) of section
 13 330C(c)(2) of the Public Health Service Act (42 U.S.C.
 14 254c–3(c)(2)(D)) is amended by striking “and 2019” and
 15 inserting “through 2024”.

16 **TITLE V—IMPROVING THE EX-**
 17 **CHANGE OF HEALTH INFOR-**
 18 **MATION**

19 **SEC. 501. REQUIREMENT TO PROVIDE HEALTH CLAIMS,**
 20 **NETWORK, AND COST INFORMATION.**

21 (a) IN GENERAL.—Part A of title XXVII of the Pub-
 22 lic Health Service Act (42 U.S.C. 300gg et seq.) is amend-
 23 ed by inserting after section 2715A the following:

1 **“SEC. 2715B. REQUIREMENT TO PROVIDE HEALTH CLAIMS,**
 2 **NETWORK, AND COST INFORMATION.**

3 “(a) IN GENERAL.—A group health plan or a health
 4 insurance issuer offering group or individual health insur-
 5 ance coverage shall make available for access, exchange,
 6 or use without special effort, through application program-
 7 ming interfaces (or successor technology or standards),
 8 the information described in subsection (b), in the manner
 9 described in subsection (b) and otherwise consistent with
 10 this section.

11 “(b) INFORMATION.—The following information is re-
 12 quired to be made available, in such form and manner as
 13 the Secretary may specify, as described in subsection (a):

14 “(1) Historical claims, provider encounter, and
 15 payment data for each enrollee, which shall—

16 “(A) include adjudicated medical and pre-
 17 scription drug claims and equivalent encoun-
 18 ters, including all data elements contained in
 19 such transactions—

20 “(i) that were adjudicated by the
 21 group health plan or health insurance
 22 issuer during the previous 5 years or the
 23 enrollee’s entire period of enrollment in the
 24 applicable plan or coverage if such period
 25 is less than 5 years;

1 “(ii) that involve benefits managed by
2 any third party, such as a pharmacy bene-
3 fits manager or radiology benefits manager
4 that manages benefits or adjudicates
5 claims on behalf of the plan or coverage;
6 and

7 “(iii) from any other health plan or
8 health insurance coverage issued or admin-
9 istered by the same insurance issuer, in
10 which the same enrollee was enrolled dur-
11 ing the previous 5 years; and

12 “(B) be available—

13 “(i) in a single, longitudinal format
14 that is easy to understand and secure, and
15 that may update automatically, including
16 by using the standards adopted for imple-
17 mentation of section 3001(c)(5)(D)(iv);

18 “(ii) as soon as practicable, and in no
19 case later than the period of time deter-
20 mined by the Secretary, after the claim is
21 adjudicated or the data is received by the
22 health plan or health insurance issuer; and

23 “(iii) to the enrollee, and any pro-
24 viders or third-party applications or serv-
25 ices authorized by the enrollee, for 5 years

1 after the end date of the enrollee's enroll-
 2 ment in the plan or in any coverage offered
 3 by the health insurance issuer.

4 “(2) Identifying directory information for all in-
 5 network providers, including facilities and practi-
 6 tioners, that participate in the plan or coverage,
 7 which shall—

8 “(A) include—

9 “(i) the national provider identifier
 10 for in-network facilities and practitioners;
 11 and

12 “(ii) the name, address, phone num-
 13 ber, and specialty for each such facility
 14 and practitioner, based on the most recent
 15 interaction between the plan or coverage
 16 and that facility or practitioner;

17 “(B) be capable of returning a list of par-
 18 ticipating in-network facilities and practitioners,
 19 in a given specialty or at a particular facility
 20 type, within a specified geographic radius; and

21 “(C) be capable of returning the network
 22 status, when presented with identifiers for a
 23 given enrollee and facility or practitioner.

24 “(3) Estimated patient out-of-pocket costs, in-
 25 cluding costs expected to be incurred through a de-

1 ductible, copayment, coinsurance, or other form of
2 cost-sharing, for—

3 “(A) a designated set of common services
4 or episodes of care, to be established by the
5 Secretary through rulemaking, including, at a
6 minimum—

7 “(i) in the case of services provided by
8 a hospital, the 100 most common diag-
9 nosis-related groups, as used in the Medi-
10 care Inpatient Prospective Patient System
11 (or successor episode-based reimbursement
12 methodology) at that hospital, based on
13 claims data adjudicated by the group
14 health plan or health insurance issuer;

15 “(ii) in the case of services provided
16 in an outpatient setting, including radi-
17 ology, lab tests, and outpatient surgical
18 procedures, any service rendered by the fa-
19 cility or practitioner, and reimbursed by
20 the health plan or health insurance issuer;
21 and

22 “(iii) in the case of post-acute care,
23 including home health providers, skilled
24 nursing facilities, inpatient rehabilitation
25 facilities, and long-term care hospitals, the

1 patient out-of-pocket costs for an episode
 2 of care, as the Secretary may determine,
 3 which permits users to reasonably compare
 4 costs across different facility and service
 5 types; and

6 “(B) all prescription drugs currently in-
 7 cluded on any tier of the formulary of the plan
 8 or coverage.

9 “(c) AVAILABILITY AND ACCESS.—The application
 10 programming interfaces, including all data required to be
 11 made available through such interfaces, shall—

12 “(1) be made available by the applicable group
 13 health plan or health insurance issuer, at no charge,
 14 to—

15 “(A) enrollees in the group health plan or
 16 health insurance coverage;

17 “(B) third parties authorized by the en-
 18 rollee;

19 “(C) facilities and practitioners who are
 20 under contract with the plan or coverage; and

21 “(D) business associates of such facilities
 22 and practitioners, as defined in section 160.103
 23 of title 45, Code of Federal Regulations (or any
 24 successor regulations);

1 “(2) be available to enrollees in the group
 2 health plan or health insurance coverage, and to
 3 third-party applications or services facilitating such
 4 access by enrollees, during the enrollment process
 5 and for a minimum of 5 years after the end date of
 6 the enrollee’s enrollment in the plan or in any cov-
 7 erage offered by the health insurance issuer;

8 “(3) permit persistent access by third-party ap-
 9 plications or services authorized by the enrollee, for
 10 a reasonable period of time, consistent with current
 11 security practices;

12 “(4) employ the applicable content, vocabulary,
 13 and technical standards, including, as appropriate,
 14 such standards adopted by the Secretary pursuant
 15 to title XXX; and

16 “(5) employ security and authentication stand-
 17 ards, as the Secretary determines appropriate.

18 “(d) RULE OF CONSTRUCTION REGARDING PRI-
 19 VACY.—Nothing in this section shall be construed to alter
 20 existing obligations under the privacy, security, and
 21 breach notification rules promulgated under section 264(e)
 22 of the Health Insurance Portability and Accountability
 23 Act (or successor regulations), under part 2 of title 42,
 24 Code of Federal Regulations (or successor regulations),
 25 under section 444 of the General Education Provisions

1 Act (~~20 U.S.C. 1232g~~) (commonly referred to as the
 2 ‘Family Educational Rights and Privacy Act of 1974’),
 3 under the amendments made by the Genetic Information
 4 Nondiscrimination Act, or under State privacy law.”

5 (b) EFFECTIVE DATE.—Section 2715B of the Public
 6 Health Service Act, as added by subsection (a), shall take
 7 effect 1 year after the date of enactment of this Act.

8 **SEC. 502. RECOGNITION OF SECURITY PRACTICES.**

9 Part 1 of subtitle D of the Health Information Tech-
 10 nology for Economic and Clinical Health Act (~~42 U.S.C.~~
 11 ~~17931 et seq.~~) is amended by adding at the end the fol-
 12 lowing:

13 **“SEC. 13412. RECOGNITION OF SECURITY PRACTICES.**

14 “(a) IN GENERAL.—Consistent with the authority of
 15 the Secretary under sections 1176 and 1177 of the Social
 16 Security Act, when making determinations relating to
 17 fines under section 13410, decreasing the length and ex-
 18 tent of an audit under section 13411, or remedies other-
 19 wise agreed to by the Secretary, the Secretary shall con-
 20 sider whether the entity or business associate had, for not
 21 less than the previous 12 months, recognized security
 22 practices in place that may—

23 “(1) mitigate fines under section 13410;

24 “(2) result in the early, favorable termination
 25 of an audit under section 13411; and

1 “(3) limit the remedies that would otherwise be
2 agreed to in any agreement between the entity or
3 business associate and the Department of Health
4 and Human Services.

5 “(b) ADDITIONAL CONSIDERATION.—At the election
6 of the entity or business associate, the Secretary may pro-
7 vide further consideration to an entity or business asso-
8 ciate that can adequately demonstrate that such recog-
9 nized security practices were in place, as determined by
10 the Secretary.

11 “(c) DEFINITION AND MISCELLANEOUS PROVI-
12 SIONS.—

13 “(1) RECOGNIZED SECURITY PRACTICES.—The
14 term ‘recognized security practices’ means the stand-
15 ards, guidelines, best practices, methodologies, pro-
16 cedures, and processes developed under section
17 2(e)(15) of the National Institute of Standards and
18 Technology Act, the approaches promulgated under
19 section 405(d) of the Cybersecurity Information
20 Sharing Act of 2015, and any other program or
21 processes that are equivalent to such requirements
22 as may be developed through regulations. Such prac-
23 tices shall be determined by the entity or business
24 associate, except where additional consideration is
25 requested under subsection (b).

1 “(2) ~~LIMITATION.—~~Nothing in this section
2 shall be construed as providing the Secretary author-
3 ity to—

4 “~~(A)~~ increase fines under section ~~13410~~, or
5 the length, extent or quantity of audits under
6 section ~~13411~~, due to a lack of compliance with
7 the recognized security practices; or

8 “~~(B)~~ mandate, direct, or condition the
9 award of any Federal grant, contract, or pur-
10 chase, on compliance with such recognized secu-
11 rity practices.

12 “(3) ~~NO LIABILITY FOR NONPARTICIPATION.—~~
13 Nothing in this section shall be construed to subject
14 an entity or business associate to liability for elect-
15 ing not to engage in the recognized security prac-
16 tices defined by this section.

17 “(4) ~~RULE OF CONSTRUCTION.—~~Nothing in
18 this section shall be construed to limit the Sec-
19 retary’s authority to enforce the HIPAA Security
20 rule (part 160 of title 45, Code of Federal Regula-
21 tions, and subparts A and C of part 164 of such
22 title); or to supersede or conflict with an entity or
23 business associate’s obligations under the HIPAA
24 Security rule.”.

1 **SEC. 503. GAO STUDY ON THE PRIVACY AND SECURITY**
2 **RISKS OF ELECTRONIC TRANSMISSION OF IN-**
3 **DIVIDUALLY IDENTIFIABLE HEALTH INFOR-**
4 **MATION TO AND FROM ENTITIES NOT COV-**
5 **ERED BY THE HEALTH INSURANCE PORT-**
6 **ABILITY AND ACCOUNTABILITY ACT.**

7 (a) IN GENERAL.—Not later than 1 year after the
8 date of enactment of this Act, the Comptroller General
9 of the United States shall conduct a study to—

10 (1) describe the roles of Federal agencies and
11 the private sector with respect to protecting the pri-
12 vacy and security of individually identifiable health
13 information transmitted electronically to and from
14 entities not covered by the regulations promulgated
15 under section 264(e) of the Health Insurance Port-
16 ability and Accountability Act of 1996 (42 U.S.C.
17 ~~1320d–2~~ note);

18 (2) identify recent developments regarding the
19 use of application programming interfaces to access
20 individually identifiable health information, and im-
21 plications for the privacy and security of such infor-
22 mation;

23 (3) identify practices in the private sector, such
24 as terms and conditions for use, relating to the pri-
25 vacy, disclosure, and secondary uses of individually
26 identifiable health information transmitted electroni-

1 eally to or from entities, selected by an individual,
 2 that are not subject to the regulations promulgated
 3 under section 264(e) of the Health Insurance Port-
 4 ability and Accountability Act of 1996; and

5 (4) identify steps the public and private sectors
 6 can take to improve the private and secure access to
 7 and availability of individually identifiable health in-
 8 formation.

9 (b) REPORT.—Not later than 1 year after the date
 10 of enactment of this Act, the Comptroller General of the
 11 United States shall submit to Congress a report con-
 12 cerning the findings of the study conducted under sub-
 13 section (a).

14 **SEC. 504. TECHNICAL CORRECTIONS.**

15 (a) IN GENERAL.—Section 3022(b) of the Public
 16 Health Service Act (42 U.S.C. 300jj–52(b)) is amended
 17 by adding at the end the following new paragraph:

18 “(4) APPLICATION OF AUTHORITIES UNDER IN-
 19 SPECTOR GENERAL ACT OF 1978.—In carrying out
 20 this subsection, the Inspector General shall have the
 21 same authorities as provided under section 6 of the
 22 Inspector General Act of 1978 (5 U.S.C. App.).”

23 (b) EFFECTIVE DATE.—The amendment made by
 24 subsection (a) shall take effect as if included in the enact-

1 ment of the 21st Century Cures Act (Public Law 114–
2 255).

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) *SHORT TITLE*.—This Act may be cited as the
5 “Lower Health Care Costs Act”.

6 (b) *TABLE OF CONTENTS*.—The table of contents for
7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—ENDING SURPRISE MEDICAL BILLS

Sec. 101. Protecting patients against out-of-network deductibles in emergencies.

Sec. 102. Protection against surprise bills.

Sec. 103. Benchmark for payment.

Sec. 104. Effective date.

Sec. 105. Ending surprise air ambulance bills.

Sec. 106. Report.

TITLE II—REDUCING THE PRICES OF PRESCRIPTION DRUGS

Sec. 201. Biological product patent transparency.

Sec. 202. Orange Book modernization.

Sec. 203. Ensuring timely access to generics.

Sec. 204. Protecting access to biological products.

Sec. 205. Preventing blocking of generic drugs.

Sec. 206. Education on biological products.

Sec. 207. Biological product innovation.

Sec. 208. Clarifying the meaning of new chemical entity.

Sec. 209. Streamlining the transition of biological products.

Sec. 210. Orphan drug clarification.

Sec. 211. Prompt approval of drugs related to safety information.

Sec. 212. Conditions of use for biosimilar biological products.

Sec. 213. Modernizing the labeling of certain generic drugs.

Sec. 214. Actions for delays of generic drugs and biosimilar biological products.

Sec. 215. Reducing the price of prescription drugs.

TITLE III—IMPROVING TRANSPARENCY IN HEALTH CARE

Sec. 301. Increasing transparency by removing gag clauses on price and quality information.

Sec. 302. Banning anticompetitive terms in facility and insurance contracts that limit access to higher quality, lower cost care.

Sec. 303. Designation of a nongovernmental, nonprofit transparency organization to lower Americans’ health care costs.

Sec. 304. Protecting patients and improving the accuracy of provider directory information.

Sec. 305. Timely bills for patients.

Sec. 306. Health plan oversight of pharmacy benefit manager services.

- Sec. 307. Government Accountability Office study on profit- and revenue-sharing in health care.*
- Sec. 308. Disclosure of direct and indirect compensation for brokers and consultants to employer-sponsored health plans and enrollees in plans on the individual market.*
- Sec. 309. Ensuring enrollee access to cost-sharing information.*
- Sec. 310. Strengthening parity in mental health and substance use disorder benefits.*
- Sec. 311. Technical amendments.*
- Sec. 312. Third-party administrators.*
- Sec. 313. Group health plan reporting requirements.*
- Sec. 314. Study by Comptroller General of United States.*

TITLE IV—IMPROVING PUBLIC HEALTH

- Sec. 401. Improving awareness of disease prevention.*
- Sec. 402. Grants to address vaccine-preventable diseases.*
- Sec. 403. Guide on evidence-based strategies for public health department obesity prevention programs.*
- Sec. 404. Expanding capacity for health outcomes.*
- Sec. 405. Public health data system modernization.*
- Sec. 406. Innovation for maternal health.*
- Sec. 407. Training for health care providers.*
- Sec. 408. Study on training to reduce and prevent discrimination.*
- Sec. 409. Perinatal quality collaboratives.*
- Sec. 410. Integrated services for pregnant and postpartum women.*
- Sec. 411. Extension for community health centers, the national health service corps, and teaching health centers that operate GME programs.*
- Sec. 412. Other programs.*
- Sec. 413. Native American suicide prevention.*
- Sec. 414. Minimum age of sale of tobacco products.*
- Sec. 415. Sale of tobacco products to individuals under the age of 21.*

TITLE V—IMPROVING THE EXCHANGE OF HEALTH INFORMATION

- Sec. 501. Requirement to provide health claims, network, and cost information.*
- Sec. 502. Recognition of security practices.*
- Sec. 503. GAO study on the privacy and security risks of electronic transmission of individually identifiable health information to and from entities not covered by the Health Insurance Portability and Accountability Act.*
- Sec. 504. Technical corrections.*
- Sec. 505. Public meeting.*

- 1 **TITLE I—ENDING SURPRISE**
- 2 **MEDICAL BILLS**
- 3 **SEC. 101. PROTECTING PATIENTS AGAINST OUT-OF-NET-**
- 4 **WORK DEDUCTIBLES IN EMERGENCIES.**
- 5 Section 2719A(b) of the Public Health Service Act (42
- 6 U.S.C. 300gg–19a) is amended—

1 (1) *in paragraph (1)—*

2 (A) *in the matter preceding subparagraph*
3 (A), *by inserting “or a freestanding emergency*
4 *room” after “hospital”; and*

5 (B) *in subparagraph (C)—*

6 (i) *in clause (ii)(I), by inserting “or*
7 *freestanding emergency room” after “emer-*
8 *gency department”; and*

9 (ii) *in subparagraph (C)(ii)(II), by*
10 adding, *“a deductible,” after “(expressed*
11 *as”; and*

12 (2) *in paragraph (2)(B)—*

13 (A) *in clause (i)—*

14 (i) *by inserting “or freestanding emer-*
15 *gency room” after “hospital”; and*

16 (ii) *by inserting “or freestanding emer-*
17 *gency room” after “emergency department”;*
18 *and*

19 (B) *in clause (ii), by inserting “or free-*
20 *standing emergency room” after “hospital”.*

21 **SEC. 102. PROTECTION AGAINST SURPRISE BILLS.**

22 (a) *PHSA.—Section 2719A of the Public Health Serv-*
23 *ice Act (42 U.S.C. 300gg–19a) is amended by adding at*
24 *the end the following:*

25 “(e) *OUT-OF-NETWORK ANCILLARY SERVICES.—*

1 “(1) *COVERAGE OF SERVICES.*—Subject to sub-
 2 section (h), in the case of an enrollee in a group
 3 health plan or group or individual health insurance
 4 coverage who receives out-of-network ancillary services
 5 at an in-network facility, including any referrals for
 6 diagnostic services, and such services would be covered
 7 under such plan or coverage if provided in-network—

8 “(A) the cost-sharing requirement (expressed
 9 as a copayment amount, coinsurance rate, or de-
 10 ductible) with respect to such services shall be the
 11 same requirement that would apply if such serv-
 12 ices were provided by an in-network practi-
 13 tioner, and any coinsurance or deductible shall
 14 be based on in-network rates; and

15 “(B) amounts paid toward such cost-shar-
 16 ing shall be counted towards the in-network de-
 17 ductible and in-network out-of-pocket maximum
 18 amount, as applicable, under the plan or cov-
 19 erage for the plan year.

20 “(2) *NOTICE BEFORE PROVIDING NON-EMER-*
 21 *GENCY SERVICES.*—Subject to subsection (h), in the
 22 case of an enrollee in a group health plan or group
 23 or individual health insurance coverage who receives
 24 out-of-network, non-emergency services that are not
 25 ancillary services, from an out-of-network provider at

1 *an in-network facility, and such services would be*
2 *covered under such plan or coverage if provided in-*
3 *network, the cost-sharing requirement (expressed as a*
4 *copayment amount, coinsurance rate, or deductible)*
5 *with respect to such services shall be the same require-*
6 *ment that would apply if such services were provided*
7 *by an in-network practitioner, and any coinsurance*
8 *or deductible shall be based on in-network rates, un-*
9 *less, as soon as practicable, and in no case later than*
10 *48 hours prior to providing non-emergency services*
11 *that are not ancillary services—*

12 *“(A) the in-network facility provides to the*
13 *enrollee who is scheduled to receive such services*
14 *notice that—*

15 *“(i) is provided in paper or electronic*
16 *form (and including electronic notification*
17 *whenever practicable);*

18 *“(ii) states that such service will be*
19 *provided out-of-network;*

20 *“(iii) includes the estimated amount*
21 *that such practitioner or facility may*
22 *charge the enrollee for such services; and*

23 *“(iv) provides the option to affirma-*
24 *tively consent to receiving such services*
25 *from such practitioner or facility;*

1 “(B) such enrollee signs such notice con-
 2 senting to receive such services from an out-of-
 3 network provider at an in-network facility, and
 4 acknowledging that the out-of-network services
 5 may be covered at an out-of-network cost-sharing
 6 amount, requiring higher cost-sharing obliga-
 7 tions of the enrollee than if the service were pro-
 8 vided by an in-network practitioner or facility;
 9 and

10 “(C) such facility maintains documentation
 11 of the enrollee’s signature or confirmation of re-
 12 ceipt of such information under subparagraph
 13 (B) in the enrollee’s patient record for 2 years
 14 after the date of services.

15 “(3) DEFINITION.—For purposes of this sub-
 16 section, the term ‘facility’ has the meaning given the
 17 term ‘health care facility’ in section 2729A(c).

18 “(f) COVERAGE OF OUT-OF-NETWORK SERVICES FOR
 19 ENROLLEES ADMITTED AFTER EMERGENCY SERVICES.—

20 “(1) PROTECTION FOR ENROLLEES ADMITTED TO
 21 THE HOSPITAL FOR EMERGENCY SERVICES PRIOR TO
 22 STABILIZATION.—In the case of an enrollee in a
 23 group health plan or group or individual health in-
 24 surance coverage who receives emergency services, or
 25 maternal care for a woman in labor, in the emer-

1 *gency department of an out-of-network facility and*
 2 *has not been stabilized (within the meaning of sub-*
 3 *section (b)(2)(C)), if the patient is subsequently ad-*
 4 *mitted to the out-of-network facility for care, the cost-*
 5 *sharing requirement (expressed as a copayment*
 6 *amount, coinsurance rate, or deductible) with respect*
 7 *to any out-of-network services provided to the enrollee*
 8 *prior to being stable and in a condition to receive in-*
 9 *formation under (2), is the same requirement that*
 10 *would apply as under subsection (b)(2)(C)(ii)(II).*

11 *“(2) NOTICE AND CONSENT.—*

12 *“(A) IN GENERAL.—Subject to subsection*
 13 *(h), in the case of an enrollee in a group health*
 14 *plan or group or individual health insurance*
 15 *coverage who receives emergency services, or ma-*
 16 *ternal care for a woman in labor, in the emer-*
 17 *gency department of an out-of-network facility*
 18 *and has been stabilized (within the meaning of*
 19 *subsection (b)(2)(C)), if the patient is subse-*
 20 *quently admitted to the out-of-network facility*
 21 *for care, the cost-sharing requirement (expressed*
 22 *as a copayment amount, coinsurance rate, or de-*
 23 *ductible) with respect to any out-of-network serv-*
 24 *ices is the same requirement that would apply if*
 25 *such services were provided by an in-network*

1 *provider, unless the enrollee, once stable and in*
2 *a condition to receive such information, includ-*
3 *ing having sufficient mental capacity—*

4 *“(i) has been provided by the facility,*
5 *prior to the provision of any post-stabiliza-*
6 *tion, out-of-network service at such facility,*
7 *with—*

8 *“(I) paper or electronic notifica-*
9 *tion that the practitioner or facility is*
10 *an out-of-network health care provider*
11 *and the out-of-network rate of the pro-*
12 *vider, as applicable, and the option to*
13 *affirmatively consent to receiving serv-*
14 *ices from such practitioner or facility;*
15 *and*

16 *“(II) the estimated amount that*
17 *such provider may charge the partici-*
18 *pant, beneficiary, or enrollee for such*
19 *services involved;*

20 *“(ii) has been provided by the plan or*
21 *coverage, prior to the provision of any post-*
22 *stabilization, out-of-network service at such*
23 *facility, with—*

24 *“(I) paper or electronic notifica-*
25 *tion (and including electronic notifica-*

1 *tion whenever practicable) that the*
2 *practitioner or facility is an out-of-net-*
3 *work health care provider, and the op-*
4 *tion to affirmatively consent to receiv-*
5 *ing services from such practitioner or*
6 *facility;*

7 *“(II) a list of in-network practi-*
8 *tioners or facilities in the relevant geo-*
9 *graphic area that could provide the*
10 *same services, and an option for a re-*
11 *ferral to such providers; and*

12 *“(III) information about whether*
13 *prior authorization or other care man-*
14 *agement limitations may be required*
15 *in advance of receiving in-network*
16 *services at the facility;*

17 *“(iii) has acknowledged, in writing,*
18 *that the out-of-network services provided*
19 *after the individual has been stabilized may*
20 *not be covered or may be covered at an out-*
21 *of-network cost-sharing amount, requiring*
22 *higher cost-sharing obligations of the en-*
23 *rollee than if the service were provided at*
24 *an in-network facility.*

1 “(B) *REQUIREMENTS OF NOTICE.*—*The no-*
2 *tice under subparagraph (A) shall be in a format*
3 *determined by the Secretary to give a reasonable*
4 *layperson clear comprehension of the terms of the*
5 *agreement, including all possible financial re-*
6 *sponsibilities, including the requirements that*
7 *the notice—*

8 “(i) *does not exceed one page in length;*

9 “(ii) *is readily identifiable for its pur-*
10 *pose and as a contract of consent;*

11 “(iii) *clearly states that consent to po-*
12 *tential out-of-network charges is optional*
13 *and that the enrollee has the choice to trans-*
14 *fer to an in-network facility;*

15 “(iv) *includes an estimate of the*
16 *amount that such provider will charge the*
17 *participant, beneficiary, or enrollee for such*
18 *services involved; and*

19 “(v) *be available in the 15 most com-*
20 *mon languages in the facility’s geographic*
21 *area, with the facility making a good faith*
22 *effort to provide oral notice in the enrollee’s*
23 *primary language if it is not one of such 15*
24 *languages.*

1 “(C) *MAINTENANCE OF RECORDS.*—A facil-
 2 ity shall maintain documentation of notice given
 3 to an enrollee pursuant to this subsection and
 4 the enrollee’s confirmation of receipt of such in-
 5 formation in the enrollee’s patient record for 2
 6 years after the date of services.

7 “(3) *RULEMAKING.*—Not later than 6 months
 8 after the date of enactment of the Lower Health Care
 9 Costs Act, the Secretary shall issue regulations to
 10 carry out this subsection, which shall include clari-
 11 fication on how to determine whether an individual
 12 is stabilized and the timing of the notice required
 13 under this paragraph.

14 “(g) *PROHIBITION ON BILLING MORE THAN AN IN-*
 15 *NETWORK RATE UNDER CERTAIN CIRCUMSTANCES.*—

16 “(1) *IN GENERAL.*—A facility or practitioner
 17 furnishing—

18 “(A) *emergency services, as defined in sub-*
 19 *section (b)(2), regardless of the State in which*
 20 *the patient resides;*

21 “(B) *out-of-network services at an in-net-*
 22 *work facility described in subsection (e)(1);*

23 “(C) *out-of-network services at an in-net-*
 24 *work facility described in subsection (e)(2),*
 25 *where the notice and consent for receiving such*

1 *services out-of-network did not meet the require-*
2 *ment of such subsection;*

3 *“(D) services furnished by an out-of-network*
4 *provider after an enrollee has been admitted to*
5 *the hospital for emergency services but prior to*
6 *stabilization, as described in subsection (f)(1); or*

7 *“(E) out-of-network services furnished after*
8 *the enrollee has been stabilized (within the mean-*
9 *ing of subsection (b)(2)(C)), where the notice and*
10 *option for receiving care at an alternate facility*
11 *required under subsection (f)(2) have not been*
12 *provided to the enrollee and the enrollee did not*
13 *give consent under subsection (f)(3),*
14 *may not bill an enrollee in a group health plan or*
15 *group or individual health insurance coverage for*
16 *amounts beyond the cost-sharing amount that would*
17 *apply under subsection (b)(1)(C)(ii)(II), (e)(1), (e)(2),*
18 *or (f), as applicable.*

19 *“(2) NOTICE.—A facility furnishing services de-*
20 *scribed in paragraph (1) shall provide enrollees in a*
21 *group health plan or group or individual health in-*
22 *surance coverage with a one-page notice, in 16-point*
23 *font, upon intake at the emergency room or being ad-*
24 *mitted at the facility of the prohibition on balance*
25 *billing under paragraph (1) and who to contact for*

1 *recourse if they are sent a balance bill in violation of*
 2 *such paragraph. The facility shall be responsible for*
 3 *obtaining the signature from the enrollee on such no-*
 4 *tice. The Secretary shall issue regulations within 6*
 5 *months of the date of enactment of the Lower Health*
 6 *Care Costs Act on the requirements for the notice*
 7 *under this paragraph.*

8 *“(h) MAINTAINING STATE SURPRISE BILLING PRO-*
 9 *TECTIONS.—*

10 *“(1) IN GENERAL.—Nothing in this section shall*
 11 *prevent a State from establishing or continuing in ef-*
 12 *fect, with respect to health insurance issuers, facili-*
 13 *ties, or practitioners, an alternate method under State*
 14 *law for determining the appropriate compensation for*
 15 *services described in subsection (b), (e), or (f).*

16 *“(2) ADDITIONAL APPLICATION.—In the case of*
 17 *group health plans or group or individual health in-*
 18 *surance coverage offered in a State that has not estab-*
 19 *lished an alternate method described in paragraph*
 20 *(1), such as arbitration or a benchmark, or for serv-*
 21 *ices described in subsection (b), (e), or (f) that are not*
 22 *covered by such State’s alternate method described in*
 23 *paragraph (1), the provisions of this section shall*
 24 *apply.*

1 “(3) *SELF-INSURED PLANS*.—Subsections (b), (e),
 2 and (f) shall apply to a self-insured group health
 3 plan that is not subject to State insurance regulation.

4 “(i) *DEFINITIONS*.—In this section:

5 “(1) *IN-NETWORK*.—The term ‘in-network’, with
 6 respect to a group health plan or health insurance
 7 coverage means a provider that has a contractual re-
 8 lationship with the plan.

9 “(2) *ENROLLEE*.—The term ‘enrollee’, with re-
 10 spect to health insurance coverage or a group health
 11 plan, includes a participant, dependent, or bene-
 12 ficiary.

13 “(3) *ANCILLARY SERVICES*.—The term ‘ancillary
 14 services’ means non-emergency care that is—

15 “(A) provided by anesthesiologists, patholo-
 16 gists, emergency medicine providers, intensivists,
 17 radiologists, neonatologists, hospitalists, and as-
 18 sistant surgeons, whether the care is provided by
 19 a physician or non-physician practitioner;

20 “(B) a diagnostic service (including radi-
 21 ology and lab services); or

22 “(C) provided by such other specialty prac-
 23 titioner not typically selected by the patients re-
 24 ceiving the care, which the Secretary may add

1 *periodically to such definition through rule-*
2 *making.”.*

(b) *ENFORCEMENT OF BALANCE BILLING PROHIBITIONS.*—*Part C of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–91 et seq.) is amended by adding at the end the following:*

7 “SEC. 2795. ENFORCEMENT OF BALANCE BILLING PROHIBI-
8 TIONS.

9 “(a) *IN GENERAL.*—Subject to subsection (b), a facil-
10 ity or practitioner that violates a requirement under section
11 2719A(g)(1) or fails to provide notice or obtain consent as
12 required under subsection (e)(2) or (f)(2) shall be subject
13 to a civil monetary penalty of not more than \$10,000 for
14 each act constituting such violation.

15 “(b) *PROCEDURE.*—The provisions of section 1128A of
16 the Social Security Act, other than subsections (a) and (b)
17 and the first sentence of subsection (c)(1) of such section,
18 shall apply to civil money penalties under this subsection
19 in the same manner as such provisions apply to a penalty
20 or proceeding under section 1128A of the Social Security
21 Act.

22 “(c) *SAFE HARBOR*.—

23 “(1) IN GENERAL.—The Secretary shall waive
24 the penalties described under subsection (a) with re-
25 spect to a facility or, practitioner who does not know-

1 *ingly violate, and should not have reasonably known*
 2 *it violated, section 2719A(g)(1) with respect to an en-*
 3 *rollee, if such facility or practitioner, within 30 days*
 4 *of the violation, withdraws the bill that was in viola-*
 5 *tion of section 2719A(g)(1), and, as applicable, reim-*
 6 *burses the group health plan, health insurance issuer,*
 7 *or enrollee, in an amount equal to the difference be-*
 8 *tween the amount billed and the amount allowed to*
 9 *be billed under section 2719A(g)(1), plus interest, at*
 10 *an interest rate determined by the Secretary.*

11 *“(2) HARDSHIP EXEMPTION.—The Secretary*
 12 *may establish a hardship exemption to the penalties*
 13 *under this section.*

14 *“(3) STATE ENFORCEMENT.—The Secretary shall*
 15 *wave penalties under this section with respect to a*
 16 *facility or practitioner that has already been subject*
 17 *to enforcement action under State law for a violation*
 18 *described in subsection (a).”.*

19 *(c) APPLICATION TO GRANDFATHERED PLANS.—Sec-*
 20 *tion 1251(a) of the Patient Protection and Affordable Care*
 21 *Act (42 U.S.C. 18011(a)) is amended by adding at the end*
 22 *the following:*

23 *“(5) APPLICATION OF ADDITIONAL PROVI-*
 24 *SIONS.—Subsections (b) through (h) of section 2719A*
 25 *of the Public Health Service Act (42 U.S.C. 300gg—*

1 19a) shall apply to grandfathered health plans for
 2 plan years beginning with the second plan year that
 3 begins after the date of enactment of the Lower Health
 4 Care Costs Act.”.

5 (d) *COVERAGE UNDER FEDERAL EMPLOYEES HEALTH*
 6 *BENEFITS PROGRAM.*—Section 8904 of title 5, United
 7 States Code, is amended by adding at the end the following:
 8 “(c) Any health benefits plan offered under this chapter
 9 shall be treated as a group health plan or group or indi-
 10 vidual health insurance coverage for purposes of subsections
 11 (e) through (g) of section 2719A of the Public Health Service
 12 Act (42 U.S.C. 300gg–19a) (except for paragraph (3) of
 13 such subsection (g)).”.

14 **SEC. 103. BENCHMARK FOR PAYMENT.**

15 (a) *IN GENERAL.*—Subpart II of part A of title XXVII
 16 of the Public Health Service Act (42 U.S.C. 300gg–11 et
 17 seq.) is amended by adding at the end the following:

18 **“SEC. 2729A. BENCHMARK FOR PAYMENT.**

19 “(a) *ESTABLISHMENT OF BENCHMARK.*—A group
 20 health plan or health insurance issuer offering group or in-
 21 dividual health insurance coverage shall pay providers, in-
 22 cluding facilities and practitioners, furnishing services for
 23 which such facilities and practitioners are prohibited under
 24 section 2719A(g) from billing enrollees for amounts beyond
 25 the cost-sharing amount that would apply under subsection

1 (b)(1)(C)(ii)(II), (e), or (f) of section 2719A, the median in-
 2 network rate for such services provided to enrollees, using
 3 a methodology determined under subsection (b) for the same
 4 or similar services offered by the group health plan or health
 5 insurance issuer in that geographic region. Such payment
 6 shall be made in a timely fashion in order to ensure compli-
 7 ance with sections 399V–7 and 2729D.

8 “(b) *MEDIAN IN-NETWORK RATE.*—

9 “(1) *IN GENERAL.*—For purposes of this section,
 10 the term ‘median in-network rate’ means, with respect
 11 to health care services covered by a group health plan
 12 or group or individual health insurance coverage, the
 13 median contracted rate under the applicable plan or
 14 coverage recognized under the plan or coverage as the
 15 total maximum payment for the service minus the in-
 16 network cost-sharing for such service under the plan
 17 or coverage, for the same or a similar service that is
 18 provided by a provider in the same or similar spe-
 19 cialty and in the geographic region in which the serv-
 20 ice is furnished.

21 “(2) *RULEMAKING.*—

22 “(A) *IN GENERAL.*—Not later than 1 year
 23 after the date of enactment of the Lower Health
 24 Care Costs Act, the Secretary shall, through rule-
 25 making, determine the methodology a group

1 *health plan or health insurance issuer is re-*
 2 *quired to use to determine the median in-net-*
 3 *work rate described in paragraph (1), differen-*
 4 *tiating by business line, the information the plan*
 5 *or issuer shall share with the out-of-network pro-*
 6 *vider involved when making such a determina-*
 7 *tion, and the geographic regions applied for pur-*
 8 *poses of this subsection. Such rulemaking shall*
 9 *take into account payments that are made by*
 10 *health insurance issuers that are not on a fee-for-*
 11 *service basis.*

12 “(B) *GEOGRAPHIC REGIONS.*—*In estab-*
 13 *lishing geographic regions under subparagraph*
 14 *(A), the Secretary shall consider adequate access*
 15 *to services in rural areas and health professional*
 16 *shortage areas, as defined in section 332. The*
 17 *Secretary shall consult with the National Asso-*
 18 *ciation of Insurance Commissioners in estab-*
 19 *lishing the geographic regions. The Secretary*
 20 *shall update the geographic regions periodically,*
 21 *as appropriate, taking into account the findings*
 22 *of the report under section 106 of the Lower*
 23 *Health Care Costs Act.*

24 “(3) *CERTAIN INSURERS.*—*If a group health*
 25 *plan or health insurance issuer offering group or in-*

1 *dividual health insurance coverage does not have suf-*
2 *ficient information to calculate a median in-network*
3 *rate for this service or provider type, or amount of,*
4 *claims for services (as determined by the applicable*
5 *State authority, in the case of health insurance cov-*
6 *erage, or by the Secretary of Labor, in the case of a*
7 *self-insured group health plan) covered under the list*
8 *of out-of-network services set by the State authority or*
9 *Secretary of Labor, as applicable, in a particular geo-*
10 *graphic area, such plan or issuer shall demonstrate*
11 *that it will use a database free of conflicts of interest*
12 *that has sufficient information reflecting allowed*
13 *amounts paid to individual health care providers for*
14 *relevant services provided in the applicable geo-*
15 *graphic region, and that such plan or issuer will use*
16 *that database to determine a median in-network rate.*
17 *The group health plan or health insurance issuer shall*
18 *cover the cost of accessing the database.*

19 “(4) *RULE OF CONSTRUCTION.*—*Nothing in this*
20 *subsection shall prevent a group health plan or health*
21 *insurance issuer from establishing separate calcula-*
22 *tions of a median in-network rate under paragraph*
23 *(1) for services delivered in nonhospital facilities, in-*
24 *cluding freestanding emergency rooms.*

1 “(c) *FACILITY*.—For purposes of this section, the term
 2 ‘health care facility’ or ‘facility’ includes hospitals, hospital
 3 outpatient departments, critical access hospitals, ambula-
 4 tory surgery centers, laboratories, radiology clinics, free-
 5 standing emergency rooms, and any other facility that pro-
 6 vides services that are covered under a group health plan
 7 or health insurance coverage, including settings of care sub-
 8 ject to section 2719A(b).”.

9 (b) *NON-FEDERAL GOVERNMENTAL PLANS*.—Section
 10 2722(a)(2)(E) of the Public Health Service Act (42 U.S.C.
 11 300gg–21(a)(2)(E)) is amended by inserting “, except that
 12 such election shall be available with respect to section
 13 2729A” before the period.

14 **SEC. 104. EFFECTIVE DATE.**

15 The amendments made by sections 101, 102, and 103
 16 shall take effect beginning in the second plan year that be-
 17 gins after the date of enactment of this Act.

18 **SEC. 105. ENDING SURPRISE AIR AMBULANCE BILLS.**

19 (a) *IN GENERAL*.—Part A of title XXVII of the Public
 20 Health Service Act is amended by inserting after section
 21 2719A (42 U.S.C. 300gg–19a) the following:

22 **“SEC. 2719B. ENDING SURPRISE AIR AMBULANCE BILLS.**

23 “(a) *IN GENERAL*.—In the case of an enrollee in a
 24 group health plan or group or individual health insurance
 25 coverage who receives air ambulance services from an out-

1 *of-network provider, if such services would be covered if pro-*
 2 *vided by an in-network provider—*

3 “(1) *the cost-sharing requirement (expressed as a*
 4 *copayment amount, coinsurance rate, or deductible)*
 5 *with respect to such services shall be the same require-*
 6 *ment that would apply if such services were provided*
 7 *by an in-network practitioner, and any coinsurance*
 8 *or deductible shall be based on in-network rates; and*

9 “(2) *such cost-sharing amounts shall be counted*
 10 *towards the in-network deductible and in-network*
 11 *out-of-pocket maximum amount under the plan or*
 12 *coverage for the plan year.*

13 “(b) *PAYMENT RATE.—A group health plan or health*
 14 *insurance issuer shall pay for air ambulance services for*
 15 *purposes of subsection (a) at the median in-network as de-*
 16 *finied in subsection (c).*

17 “(c) *MEDIAN IN-NETWORK RATE.—*

18 “(1) *IN GENERAL.—For purposes of this section,*
 19 *the term ‘median in-network rate’ means, with respect*
 20 *to air ambulance services covered by a group health*
 21 *plan or group or individual health insurance cov-*
 22 *erage, the median contracted rate under the applica-*
 23 *ble plan or coverage recognized under the plan or cov-*
 24 *erage as the total maximum payment for the service,*
 25 *minus the in-network cost-sharing for such service*

1 under the plan or coverage, for the same or a similar
 2 service that is provided by a provider in the same or
 3 similar specialty, and in the geographic region in
 4 which the service is furnished.

5 “(2) RULEMAKING.—

6 “(A) IN GENERAL.—Not later than 6
 7 months after the date of enactment of the Lower
 8 Health Care Costs Act, the Secretary shall,
 9 through rulemaking, determine the methodology
 10 a group health plan or health insurance issuer is
 11 required to use to determine the median in-net-
 12 work rate described in paragraph (1), the infor-
 13 mation the plan or issuer shall share with the
 14 out-of-network provider involved when making
 15 such a determination, and the geographic regions
 16 applied for purposes of this subsection. Such
 17 rulemaking shall take into account payments
 18 that are made by issuers that are not on a fee-
 19 for-service basis.

20 “(B) GEOGRAPHIC REGIONS.—In estab-
 21 lishing geographic regions as described in sub-
 22 paragraph (A), the Secretary shall consider ade-
 23 quate access to services in rural areas. The Sec-
 24 retary shall consult with the National Associa-
 25 tion of Insurance Commissioners in establishing

1 *the geographic regions. The Secretary shall up-*
2 *date the geographic regions periodically, as ap-*
3 *propriate, taking into account the findings of the*
4 *report under section 106 of the Lower Health*
5 *Care Costs Act.*

6 “(3) *CERTAIN INSURERS.—If a group health*
7 *plan or health insurance issuer offering group or in-*
8 *dividual health insurance coverage does not have suf-*
9 *ficient information to calculate a median in-network*
10 *rate for this service or provider type, or amount of,*
11 *claims for services (as determined by the applicable*
12 *State authority, in the case of health insurance cov-*
13 *erage, or by the Secretary of Labor, in the case of a*
14 *self-insured group health plan) covered under the list*
15 *of out-of-network services set by the State authority or*
16 *Secretary of Labor, as applicable, in a particular geo-*
17 *graphic area, such plan or issuer shall demonstrate*
18 *that it will use a database free of conflicts of interest*
19 *that has sufficient information reflecting allowed*
20 *amounts paid to individual health care providers for*
21 *relevant services provided in the applicable geo-*
22 *graphic region, and that such plan or issuer will use*
23 *that database to determine a median in-network rate.*
24 *The group health plan or health insurance issuer shall*
25 *cover the cost of accessing the database.*

1 “(4) *CLARIFICATION.*—For purposes of this sub-
2 section, the Secretary may define geographic regions
3 that are different from the geographic regions identi-
4 fied for purposes of section 2729A(b) to ensure that
5 an adequate number of air ambulance services are in-
6 network in each geographic region so that a median
7 in-network rate for air ambulance services may be
8 calculated for each such region.

9 “(d) *COST-SHARING LIMITATION.*—An air ambulance
10 service provider may not bill an enrollee in a group health
11 plan or group or individual health insurance coverage for
12 amounts beyond the cost-sharing amount that applies under
13 subsection (a).

14 “(e) *ENFORCEMENT.*—

15 “(1) *IN GENERAL.*—Subject to paragraph (2), an
16 air ambulance service provider that violates sub-
17 section (d) shall be subject to a civil monetary penalty
18 of not more than \$10,000 for each act constituting
19 such violation.

20 “(2) *PROCEDURE.*—The provisions of section
21 1128A of the Social Security Act, other than sub-
22 sections (a) and (b) and the first sentence of sub-
23 section (c)(1) of such section, shall apply to civil
24 money penalties under this subsection in the same
25 manner as such provisions apply to a penalty or pro-

1 ceeding under section 1128A of the Social Security
2 Act.

3 “(3) *SAFE HARBOR.*—The Secretary shall waive
4 the penalties described under paragraph (1) with re-
5 spect to a air ambulance service provider who un-
6 knowingly violates subsection (d) with respect to an
7 enrollee, if such air ambulance service provider with-
8 in 30 days of the violation, withdraws the bill that
9 was in violation of subsection (d), and, as applicable,
10 reimburses the group health plan, health insurance
11 issuer, or enrollee, as applicable, in an amount equal
12 to the amount billed in violation of subsection (d),
13 plus interest, at an interest rate determined by the
14 Secretary.”.

15 (b) *EFFECTIVE DATE.*—Section 2719B of the Public
16 Health Service Act, as added by subsection (a), shall take
17 effect on the date that is 1 year after the date of enactment
18 of this Act.

19 **SEC. 106. REPORT.**

20 Not later than 1 year after the effective date described
21 in section 104, and annually for the following 4 years, the
22 Secretary of Health and Human Services, in consultation
23 with the Federal Trade Commission and the Attorney Gen-
24 eral, shall—

25 (1) conduct a study on—

1 (A) the effects of the amendments made by
2 sections 101, 102, 103, and 105, including any
3 patterns of vertical or horizontal integration of
4 health care facilities, providers, group health
5 plans, or health insurance issuers;

6 (B) the effects of the amendments made by
7 sections 101, 102, 103, and 105 on overall health
8 care costs;

9 (C) the effects of the amendments made by
10 sections 101, 102, 103, and 105 on access to serv-
11 ices, including specialty services, in rural areas
12 and health professional shortage areas as defined
13 in section 332; and

14 (D) recommendations, made in consultation
15 with the Secretary of Labor and the Secretary of
16 the Treasury, for effective enforcement of 2729A
17 of the Public Health Service Act, as added by
18 section 103, including potential challenges to ad-
19 dressing anti-competitive consolidation by health
20 care facilities, providers, group health plans, or
21 health insurance issuers; and

22 (2) submit a report on such study to the Com-
23 mittee on Health, Education, Labor, and Pensions,
24 the Committee on Commerce, Science, and Transpor-
25 tation, the Committee on Finance, and the Committee

1 *on the Judiciary of the Senate and the Committee on*
 2 *Education and Labor, the Committee on Energy and*
 3 *Commerce, the Committee on Ways and Means, and*
 4 *the Committee on the Judiciary of the House of Rep-*
 5 *resentatives.*

6 ***TITLE II—REDUCING THE***
 7 ***PRICES OF PRESCRIPTION***
 8 ***DRUGS***

9 ***SEC. 201. BIOLOGICAL PRODUCT PATENT TRANSPARENCY.***

10 *(a) IN GENERAL.—Section 351 of the Public Health*
 11 *Service Act (42 U.S.C. 262) is amended by adding at the*
 12 *end the following:*

13 *“(o) ADDITIONAL REQUIREMENTS WITH RESPECT TO*
 14 *PATENTS.—*

15 *“(1) APPROVED APPLICATION HOLDER LISTING*
 16 *REQUIREMENTS.—*

17 *“(A) IN GENERAL.—Beginning on the date*
 18 *of enactment of the Lower Health Care Costs Act,*
 19 *within 60 days of approval of an application*
 20 *under subsection (a) or (k), the holder of such*
 21 *approved application shall submit to the Sec-*
 22 *retary a list of each patent required to be dis-*
 23 *closed (as described in paragraph (3)).*

24 *“(B) PREVIOUSLY APPROVED OR LICENSED*
 25 *BIOLOGICAL PRODUCTS.—*

1 “(i) *PRODUCTS LICENSED UNDER SEC-*
 2 *TION 351 OF THE PHSA.*—Not later than 30
 3 *days after the date of enactment of the*
 4 *Lower Health Care Costs Act, the holder of*
 5 *a biological product license that was ap-*
 6 *proved under subsection (a) or (k) before the*
 7 *date of enactment of such Act shall submit*
 8 *to the Secretary a list of each patent re-*
 9 *quired to be disclosed (as described in para-*
 10 *graph (3)).*

11 “(ii) *PRODUCTS APPROVED UNDER*
 12 *SECTION 505 OF THE FFDCA.*—Not later
 13 *than 30 days after March 23, 2020, the*
 14 *holder of an approved application for a bio-*
 15 *logical product under section 505 of the*
 16 *Federal Food, Drug, and Cosmetic Act that*
 17 *is deemed to be a license for the biological*
 18 *product under this section on March 23,*
 19 *2020, shall submit to the Secretary a list of*
 20 *each patent required to be disclosed (as de-*
 21 *scribed in paragraph (3)).*

22 “(C) *UPDATES.*—The holder of a biological
 23 *product license that is the subject of an applica-*
 24 *tion under subsection (a) or (k) shall submit to*
 25 *the Secretary a list that includes—*

1 “(i) any patent not previously required
2 to be disclosed (as described in paragraph
3 (3)) under subparagraph (A) or (B), as ap-
4 plicable, within 30 days of the earlier of—

5 “(I) the date of issuance of such
6 patent by the United States Patent
7 and Trademark Office; or

8 “(II) the date of approval of a
9 supplemental application for the bio-
10 logical product; and

11 “(ii) any patent, or any claim with re-
12 spect to a patent, included on the list pur-
13 suant to this paragraph, that the Patent
14 Trial and Appeal Board of the United
15 States Patent and Trademark Office deter-
16 mines in a written decision to cancel as
17 unpatentable, within 30 days of such deci-
18 sion.

19 “(2) PUBLICATION OF INFORMATION.—

20 “(A) IN GENERAL.—Within 1 year of the
21 date of enactment of the Lower Health Care
22 Costs Act, the Secretary shall publish and make
23 available to the public a single, easily searchable
24 list that includes—

1 “(i) the official and proprietary name
2 of each biological product licensed, or
3 deemed to be licensed, under subsection (a)
4 or (k);

5 “(ii) with respect to each biological
6 product described in clause (i), each patent
7 submitted in accordance with paragraph
8 (1);

9 “(iii) the date of licensure and appli-
10 cation number for each such biological prod-
11 uct;

12 “(iv) the marketing status, dosage
13 form, route of administration, strength,
14 and, if applicable, reference product, for
15 each such biological product;

16 “(v) the licensure status for each such
17 biological product, including whether the li-
18 cense at the time of listing is approved,
19 withdrawn, or revoked;

20 “(vi) with respect to each such biologi-
21 cal product, any period of exclusivity under
22 paragraph (6), (7)(A), or (7)(B) of sub-
23 section (k) of this section or section 527 of
24 the Federal Food, Drug, and Cosmetic Act,
25 and any extension of such period in accord-

1 *ance with subsection (m) of this section, for*
2 *which the Secretary has determined such bi-*
3 *ological product to be eligible, and the date*
4 *on which such exclusivity expires;*

5 *“(vii) any determination of biosimi-*
6 *larity or interchangeability for each such*
7 *biological product; and*

8 *“(viii) information regarding approved*
9 *indications for each such biological product,*
10 *in such manner as the Secretary determines*
11 *appropriate.*

12 *“(B) UPDATES.—Every 30 days after the*
13 *publication of the first list under subparagraph*
14 *(A), the Secretary shall revise the list to in-*
15 *clude—*

16 *“(i)(I) each biological product licensed*
17 *under subsection (a) or (k) during the 30-*
18 *day period; and*

19 *“(II) with respect to each biological*
20 *product described in subclause (I), the infor-*
21 *mation described in clauses (i) through*
22 *(viii) of subparagraph (A); and*

23 *“(ii) any updates to information pre-*
24 *viously published in accordance with sub-*
25 *paragraph (A).*

1 “(C) *NONCOMPLIANCE.—Beginning* 18
2 *months after the date of enactment of the Lower*
3 *Health Care Costs Act, the Secretary, in con-*
4 *sultation with the Director of the United States*
5 *Patent and Trademark Office, shall publish and*
6 *make available to the public a list of any holders*
7 *of biological product licenses, and the cor-*
8 *responding biological product or products, that*
9 *failed to submit information as required under*
10 *paragraph (1), including any updates required*
11 *under paragraph (1)(C), in such manner and*
12 *format as the Secretary determines appropriate.*
13 *If information required under paragraph (1) is*
14 *submitted following publication of such list, the*
15 *Secretary shall remove such holders of such bio-*
16 *logical product licenses from the public list in a*
17 *reasonable period of time.*

18 “(3) *PATENTS REQUIRED TO BE DISCLOSED.—In*
19 *this section, a ‘patent required to be disclosed’ is any*
20 *patent for which the holder of a biological product li-*
21 *cence approved under subsection (a) or (k), or a bio-*
22 *logical product application approved under section*
23 *505 of the Federal Food, Drug, and Cosmetic Act and*
24 *deemed to be a license for a biological product under*
25 *this section on March 23, 2020, believes a claim of*

1 *patent infringement could reasonably be asserted by*
 2 *the holder, or by a patent owner that has granted an*
 3 *exclusive license to the holder with respect to the bio-*
 4 *logical product that is the subject of such license, if*
 5 *a person not licensed by the owner engaged in the*
 6 *making, using, offering to sell, selling, or importing*
 7 *into the United States of the biological product that*
 8 *is the subject of such license.”.*

9 (b) *DISCLOSURE OF PATENTS.*—Section
 10 *351(l)(3)(A)(i) of the Public Health Service Act (42 U.S.C.*
 11 *262(l)(3)(A)(i)) is amended by inserting “included in the*
 12 *list provided by the reference product sponsor under sub-*
 13 *section (o)(1)” after “a list of patents”.*

14 (c) *REVIEW AND REPORT ON NONCOMPLIANCE.*—Not
 15 *later than 30 months after the date of enactment of this*
 16 *Act, the Secretary shall—*

17 (1) *solicit public comments regarding appro-*
 18 *priate remedies, in addition to the publication of the*
 19 *list under subsection (o)(2)(C) of section 351 of the*
 20 *Public Health Service Act (42 U.S.C. 262), as added*
 21 *by subsection (a), with respect to holders of biological*
 22 *product licenses who fail to timely submit informa-*
 23 *tion as required under subsection (o)(1) of such sec-*
 24 *tion 351, including any updates required under sub-*
 25 *paragraph (C) of such subsection (o)(1); and*

1 (2) *submit to Congress an evaluation of com-*
 2 *ments received under paragraph (1) and the rec-*
 3 *ommendations of the Secretary concerning appro-*
 4 *priate remedies.*

5 (d) *REGULATIONS.—The Secretary of Health and*
 6 *Human Services may promulgate regulations to carry out*
 7 *subsection (o) of section 351 of the Public Health Service*
 8 *Act (42 U.S.C. 262), as added by subsection (a).*

9 (e) *RULE OF CONSTRUCTION.—Nothing in this Act, in-*
 10 *cluding an amendment made by this Act, shall be construed*
 11 *to require or allow the Secretary of Health and Human*
 12 *Services to delay the licensing of a biological product under*
 13 *section 351 of the Public Health Service Act (42 U.S.C.*
 14 *262).*

15 **SEC. 202. ORANGE BOOK MODERNIZATION.**

16 (a) *SUBMISSION OF PATENT INFORMATION FOR BRAND*
 17 *NAME DRUGS.—*

18 (1) *IN GENERAL.—Paragraph (1) of section*
 19 *505(b) of the Federal Food, Drug, and Cosmetic Act*
 20 *(21 U.S.C. 355(b)) is amended to read as follows:*

21 “(b)(1)(A) *Any person may file with the Secretary an*
 22 *application with respect to any drug subject to the provi-*
 23 *sions of subsection (a). Such persons shall submit to the*
 24 *Secretary as part of the application—*

1 “(i) full reports of investigations which have
2 been made to show whether or not such drug is safe
3 for use and whether such drug is effective in use;

4 “(ii) a full list of the articles used as components
5 of such drug;

6 “(iii) a full statement of the composition of such
7 drug;

8 “(iv) a full description of the methods used in,
9 and the facilities and controls used for, the manufac-
10 ture, processing, and packing of such drug;

11 “(v) such samples of such drug and of the arti-
12 cles used as components thereof as the Secretary may
13 require;

14 “(vi) specimens of the labeling proposed to be
15 used for such drug;

16 “(vii) any assessments required under section
17 505B; and

18 “(viii) the patent number and expiration date, of
19 each patent for which a claim of patent infringement
20 could reasonably be asserted if a person not licensed
21 by the owner engaged in the manufacture, use, or sale
22 of the drug, and that—

23 “(I) claims the drug for which the applicant
24 submitted the application and is a drug sub-
25 stance patent or a drug product patent; or

1 “(II) claims the method of using the drug
2 for which approval is sought or has been granted
3 in the application.

4 “(B) If an application is filed under this subsection
5 for a drug, and a patent of the type described in subpara-
6 graph (A)(viii) that claims such drug or a method of using
7 such drug is issued after the filing date, the applicant shall
8 amend the application to include such patent informa-
9 tion.”.

10 (2) *GUIDANCE.*—The Secretary of Health and
11 Human Services shall, in consultation with the Direc-
12 tor of the National Institutes of Health and with rep-
13 resentatives of the drug manufacturing industry, re-
14 view and develop guidance, as appropriate, on the in-
15 clusion of women and minorities in clinical trials re-
16 quired under subsection (b)(1)(A)(i) of section 505 of
17 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 355), as amended by paragraph (1).

19 (b) *CONFORMING CHANGES TO REQUIREMENTS FOR*
20 *SUBSEQUENT SUBMISSION OF PATENT INFORMATION.*—
21 Section 505(c)(2) of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 355(c)(2)) is amended—

23 (1) by inserting before the first sentence the fol-
24 lowing: “Not later than 30 days after the date of ap-
25 proval of an application under subsection (b), the

1 holder of the approved application shall file with the
 2 Secretary the patent number and the expiration date
 3 of any patent described in subclause (I) or (II) of sub-
 4 section (b)(1)(A)(viii), except that a patent that is
 5 identified as claiming a method of using such drug
 6 shall be filed only if the patent claims a method of
 7 use approved in the application. The holder of the ap-
 8 proved application shall file with the Secretary the
 9 patent number and the expiration date of any patent
 10 described in subclause (I) or (II) of subsection
 11 (b)(1)(A)(viii) that is issued after the date of ap-
 12 proval of the application, not later than 30 days after
 13 the date of issuance of the patent, except that a patent
 14 that claims a method of using such drug shall be filed
 15 only if approval for such use has been granted in the
 16 application.”;

17 (2) by inserting after “the patent number and
 18 the expiration date of any patent which” the fol-
 19 lowing: “fulfills the criteria in subsection (b) and”;

20 (3) by inserting after the third sentence (as
 21 amended by paragraph (1)) the following: “Patent in-
 22 formation that is not the type of patent information
 23 required by subsection (b)(1)(A)(viii) shall not be sub-
 24 mitted under this paragraph.”; and

1 (4) by inserting after “could not file patent in-
 2 formation under subsection (b) because no patent” the
 3 following: “of the type required to be submitted in
 4 subsection (b)(1)(A)(viii)”.

5 (c) *LISTING OF EXCLUSIVITIES*.—Subparagraph (A) of
 6 section 505(j)(7) of the Federal Food, Drug, and Cosmetic
 7 Act (21 U.S.C. 355(j)(7)) is amended by adding at the end
 8 the following:

9 “(iv) For each drug included on the list, the Secretary
 10 shall specify any exclusivity period that is applicable, for
 11 which the Secretary has determined the expiration date,
 12 and for which such period has not yet expired under—

13 “(I) clause (ii), (iii), or (iv) of subsection
 14 (c)(3)(E) of this section;

15 “(II) clause (iv) or (v) of paragraph (5)(B) of
 16 this subsection;

17 “(III) clause (ii), (iii), or (iv) of paragraph
 18 (5)(F) of this subsection;

19 “(IV) section 505A;

20 “(V) section 505E;

21 “(VI) section 527(a); or

22 “(VII) subsection (u)”.

23 (d) *ORANGE BOOK UPDATES WITH RESPECT TO IN-*
 24 *VALIDATED PATENTS*.—

25 (1) *IN GENERAL*.—

1 (A) *AMENDMENTS.*—Section 505(j)(7)(A) of
2 the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 355(j)(7)(A)), as amended by subsection
4 (c), is further amended by adding at the end the
5 following:

6 “(v) In the case of a listed drug for which the
7 list under clause (i) includes a patent for such drug,
8 and where the Under Secretary of Commerce for In-
9 tellectual Property and Director of the United States
10 Patent and Trademark Office have cancelled any
11 claim of the patent pursuant to a decision by the Pat-
12 ent Trial and Appeal Board in an inter partes review
13 conducted under chapter 31 of title 35, United States
14 Code, or a post-grant review conducted under chapter
15 32 of that title, and from which no appeal has been
16 taken, or can be taken, the holder of the applicable
17 approved application shall notify the Secretary, in
18 writing, within 14 days of such cancellation, and, if
19 the patent has been deemed wholly inoperative or in-
20 valid, or if a patent claim has been cancelled, the re-
21 visions required under clause (iii) shall include strik-
22 ing the patent or information regarding such patent
23 claim from the list with respect to such drug, as ap-
24 plicable, except that the Secretary shall not remove a
25 patent from the list before the expiration of any 180-

1 *day exclusivity period under paragraph (5)(B)(iv)*
 2 *that relies on a certification described in paragraph*
 3 *(2)(A)(vii)(IV) with respect to such patent.”.*

4 *(B) APPLICATION.—The amendment made*
 5 *by subparagraph (A) shall not apply with re-*
 6 *spect to any determination with respect to a pat-*
 7 *ent or patent claim that is made prior to the*
 8 *date of enactment of this Act.*

9 *(2) NO EFFECT ON FIRST APPLICANT EXCLU-*
 10 *SIVITY PERIOD.—Section 505(j)(5)(B)(iv)(I), as*
 11 *amended by section 205, is amended by adding at the*
 12 *end the following: “This subclause shall apply even if*
 13 *a patent is stricken from the list under paragraph*
 14 *(7)(A), pursuant to paragraph (7)(A)(v), provided*
 15 *that, at the time that the first applicant submitted an*
 16 *application under this subsection containing a certifi-*
 17 *cation described in paragraph (2)(A)(vii)(IV), the*
 18 *patent that was the subject of such certification was*
 19 *included in such list with respect to the listed drug.”.*

20 **SEC. 203. ENSURING TIMELY ACCESS TO GENERICS.**

21 *Section 505(q) of the Federal Food, Drug, and Cos-*
 22 *metic Act (21 U.S.C. 355(q)) is amended—*

23 *(1) in paragraph (1)—*

24 *(A) in subparagraph (A)(i), by inserting “,*
 25 *10.31,” after “10.30”;*

1 (B) in subparagraph (E)—

2 (i) by striking “application and” and
3 inserting “application or”;

4 (ii) by striking “If the Secretary” and
5 inserting the following:

6 “(i) *IN GENERAL.—If the Secretary*”;

7 and

8 (iii) by striking the second sentence
9 and inserting the following:

10 “(ii) *PRIMARY PURPOSE OF DELAY-*
11 *ING.—*

12 “(I) *IN GENERAL.—In deter-*
13 *mining whether a petition was sub-*
14 *mitted with the primary purpose of de-*
15 *laying an application, the Secretary*
16 *may consider the following factors:*

17 “(aa) *Whether the petition*
18 *was submitted in accordance with*
19 *paragraph (2)(B), based on when*
20 *the petitioner knew or reasonably*
21 *should have known the relevant*
22 *information relied upon to form*
23 *the basis of such petition.*

24 “(bb) *Whether the petitioner*
25 *has submitted multiple or serial*

1 *petitions or supplements to peti-*
2 *tions raising issues that reason-*
3 *ably could have been known to the*
4 *petitioner at the time of submis-*
5 *sion of the earlier petition or peti-*
6 *tions.*

7 “(cc) Whether the petition
8 was submitted close in time to a
9 known, first date upon which an
10 application under subsection
11 (b)(2) or (j) of this section or sec-
12 tion 351(k) of the Public Health
13 Service Act could be approved.

14 “(dd) Whether the petition
15 was submitted without relevant
16 data or information in support of
17 the scientific positions forming the
18 basis of such petition.

19 “(ee) Whether the petition
20 raises the same or substantially
21 similar issues as a prior petition
22 to which the Secretary has re-
23 sponded substantively already, in-
24 cluding if the subsequent submis-

1 *sion follows such response from*
2 *the Secretary closely in time.*

3 *“(ff) Whether the petition re-*
4 *quests changing the applicable*
5 *standards that other applicants*
6 *are required to meet, including re-*
7 *questing testing, data, or labeling*
8 *standards that are more onerous*
9 *or rigorous than the standards the*
10 *Secretary has determined to be*
11 *applicable to the listed drug, ref-*
12 *erence product, or petitioner’s*
13 *version of the same drug.*

14 *“(gg) The petitioner’s record*
15 *of submitting petitions to the*
16 *Food and Drug Administration*
17 *that have been determined by the*
18 *Secretary to have been submitted*
19 *with the primary purpose of*
20 *delay.*

21 *“(hh) Other relevant and ap-*
22 *propriate factors, which the Sec-*
23 *retary shall describe in guidance.*

24 *“(II) GUIDANCE.—The Secretary*
25 *may issue or update guidance, as ap-*

1 *appropriate, to describe factors the Sec-*
 2 *retary considers in accordance with*
 3 *subclause (II).”;*

4 *(C) by adding at the end the following:*

5 *“(iii) REFERRAL TO THE FEDERAL*
 6 *TRADE COMMISSION.—The Secretary shall*
 7 *establish procedures for referring to the Fed-*
 8 *eral Trade Commission any petition or sup-*
 9 *plement to a petition that the Secretary de-*
 10 *termines was submitted with the primary*
 11 *purpose of delaying approval of an applica-*
 12 *tion. Such procedures shall include notifica-*
 13 *tion to the petitioner by the Secretary.”;*

14 *(D) by striking subparagraph (F);*

15 *(E) by redesignating subparagraphs (G)*
 16 *through (I) as subparagraphs (F) through (H),*
 17 *respectively; and*

18 *(F) in subparagraph (H), as so redesign-*
 19 *ated, by striking “submission of this petition”*
 20 *and inserting “submission of this document”;*

21 *(2) in paragraph (2)—*

22 *(A) by redesignating subparagraphs (A)*
 23 *through (C) as subparagraphs (C) through (E),*
 24 *respectively;*

1 (B) by inserting before subparagraph (C),
 2 as so redesignated, the following:

3 “(A) *IN GENERAL.*—A person shall submit a
 4 petition to the Secretary under paragraph (1)
 5 before filing a civil action in which the person
 6 seeks to set aside, delay, rescind, withdraw, or
 7 prevent submission, review, or approval of an
 8 application submitted under subsection (b)(2) or
 9 (j) of this section or section 351(k) of the Public
 10 Health Service Act. Such petition and any sup-
 11 plement to such a petition shall describe all in-
 12 formation and arguments that form the basis of
 13 the relief requested in any civil action described
 14 in the previous sentence.

15 “(B) *TIMELY SUBMISSION OF CITIZEN PETI-*
 16 *TION.*—A petition and any supplement to a peti-
 17 tion shall be submitted within 60 days after the
 18 person knew, or reasonably should have known,
 19 the information that forms the basis of the re-
 20 quest made in the petition or supplement.”;

21 (C) in subparagraph (C), as so redesign-
 22 ated—

23 (i) in the heading, by striking “*WITHIN*
 24 *150 DAYS*”;

1 (ii) in clause (i), by striking “during
2 the 150-day period referred to in paragraph
3 (1)(F),”; and

4 (iii) by amending clause (ii) to read as
5 follows:

6 “(ii) on or after the date that is 151
7 days after the date of submission of the peti-
8 tion, the Secretary approves or has ap-
9 proved the application that is the subject of
10 the petition without having made such a
11 final decision.”;

12 (D) by amending subparagraph (D), as so
13 redesignated, to read as follows:

14 “(D) *DISMISSAL OF CERTAIN CIVIL AC-*
15 *TIONS.—*

16 “(i) *PETITION.—*If a person files a
17 civil action against the Secretary in which
18 a person seeks to set aside, delay, rescind,
19 withdraw, or prevent submission, review, or
20 approval of an application submitted under
21 subsection (b)(2) or (j) of this section or sec-
22 tion 351(k) of the Public Health Service Act
23 without complying with the requirements of
24 subparagraph (A), the court shall dismiss

1 *without prejudice the action for failure to*
2 *exhaust administrative remedies.*

3 “(ii) *TIMELINESS.*—*If a person files a*
4 *civil action against the Secretary in which*
5 *a person seeks to set aside, delay, rescind,*
6 *withdraw, or prevent submission, review, or*
7 *approval of an application submitted under*
8 *subsection (b)(2) or (j) of this section or sec-*
9 *tion 351(k) of the Public Health Service Act*
10 *without complying with the requirements of*
11 *subparagraph (B), the court shall dismiss*
12 *with prejudice the action for failure to time-*
13 *ly file a petition.*

14 “(iii) *FINAL RESPONSE.*—*If a civil ac-*
15 *tion is filed against the Secretary with re-*
16 *spect to any issue raised in a petition time-*
17 *ly filed under paragraph (1) in which the*
18 *petitioner requests that the Secretary take*
19 *any form of action that could, if taken, set*
20 *aside, delay, rescind, withdraw, or prevent*
21 *submission, review, or approval of an appli-*
22 *cation submitted under subsection (b)(2) or*
23 *(j) of this section or section 351(k) of the*
24 *Public Health Service Act before the Sec-*
25 *retary has taken final agency action on the*

petition within the meaning of subparagraph (C), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.”; and

(E) in clause (iii) of subparagraph (E), as so redesignated, by striking “as defined under subparagraph (2)(A)” and inserting “within the meaning of subparagraph (C)”;

and

(3) in paragraph (4)—

(A) by striking “EXCEPTIONS” and all that follows through “This subsection does” and inserting “EXCEPTIONS.—This subsection does”;

(B) by striking subparagraph (B); and

(C) by redesignating clauses (i) and (ii) as subparagraphs (A) and (B), respectively, and adjusting the margins accordingly.

SEC. 204. PROTECTING ACCESS TO BIOLOGICAL PRODUCTS.

Section 351(k)(7) of the Public Health Service Act (42 U.S.C. 262(k)(7)) is amended by adding at the end the following:

“(D) *DEEMED LICENSES.*—

“(i) *NO ADDITIONAL EXCLUSIVITY THROUGH DEEMING.*—An approved application that is deemed to be a license for a biological product under this section pursu-

ant to section 7002(e)(4) of the *Biologics Price Competition and Innovation Act of 2009* shall not be treated as having been first licensed under subsection (a) for purposes of subparagraphs (A) and (B).

“(ii) *APPLICATION OF LIMITATIONS ON EXCLUSIVITY.*—Subparagraph (C) shall apply with respect to a reference product referred to in such subparagraph that was the subject of an approved application that was deemed to be a license pursuant to section 7002(e)(4) of the *Biologics Price Competition and Innovation Act of 2009*.

“(iii) *APPLICABILITY.*—The exclusivity periods described in section 527, section 505A(b)(1)(A)(ii), and section 505A(c)(1)(A)(ii) of the *Federal Food, Drug, and Cosmetic Act* shall continue to apply to a biological product after an approved application for the biological product is deemed to be a license for the biological product under subsection (a) pursuant to section 7002(e)(4) of the *Biologics Price Competition and Innovation Act of 2009*.”.

1 **SEC. 205. PREVENTING BLOCKING OF GENERIC DRUGS.**

2 (a) *IN GENERAL.*—Section 505(j)(5)(B)(iv)(I) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(j)(5)(B)(iv)(I)) is amended—

5 (1) by striking “180 days after the date” and in-
6 serting “180 days after the earlier of the following:

7 “(aa) The date”; and

8 (2) by adding at the end the following:

9 “(bb) The date on which all of the fol-
10 lowing conditions are first met, provided no
11 application submitted by any first appli-
12 cant is approved on or before such date:

13 “(AA) An application for the drug
14 submitted by an applicant other than
15 a first applicant has received tentative
16 approval and could receive approval, if
17 no first applicant were eligible for 180-
18 day exclusivity under this clause, and
19 such applicant has not entered into an
20 agreement that would prevent commer-
21 cial marketing upon approval and has
22 submitted a notification to the Sec-
23 retary documenting that it has not en-
24 tered into an agreement that would
25 prevent commercial marketing.

1 “(BB) *Thirty-three months have*
2 *passed since the date of submission of*
3 *an application for the drug by one*
4 *first applicant, if there is only one*
5 *first applicant, or, in the case of more*
6 *than one first applicant, 33 months*
7 *have passed since the date of submis-*
8 *sion of all such applications.*

9 “(CC) *Approval of an application*
10 *for the drug submitted by at least one*
11 *first applicant would not be precluded*
12 *under clause (iii).”.*

13 (b) *INFORMATION.—Not later than 60 days of the date*
14 *of enactment of this Act, the Secretary of Health and*
15 *Human Services (referred to in this subsection as the “Sec-*
16 *retary”)* shall publish, as appropriate and available, infor-
17 *mation sufficient to allow applicants to assess whether the*
18 *conditions described in subitems (AA) through (CC) of sec-*
19 *tion 505(j)(5)(B)(iv)(I)(bb) of the Federal Food, Drug, and*
20 *Cosmetic Act (as amended by subsection (a)) have been or*
21 *will be satisfied for all applications where the exclusivity*
22 *period under (iv)(I) of section 505(j)(5)(B) of the Federal*
23 *Food, Drug, and Cosmetic Act (as so amended) has not ex-*
24 *pired, and shall provide updates to reflect the most recent*
25 *information available to the Secretary.*

1 **SEC. 206. EDUCATION ON BIOLOGICAL PRODUCTS.**

2 *Subpart 1 of part F of title III of the Public Health*
 3 *Service Act (42 U.S.C. 262 et seq.) is amended by adding*
 4 *at the end the following:*

5 **“SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.**

6 “(a) *INTERNET WEBSITE.—*

7 “(1) *IN GENERAL.—The Secretary may main-*
 8 *tain and operate an internet website to provide edu-*
 9 *cational materials for health care providers, patients,*
 10 *and caregivers, regarding the meaning of the terms,*
 11 *and the standards for review and licensing of, biologi-*
 12 *cal products, including biosimilar biological products*
 13 *and interchangeable biosimilar biological products.*

14 “(2) *CONTENT.—Educational materials provided*
 15 *under paragraph (1) may include—*

16 “(A) *explanations of key statutory and reg-*
 17 *ulatory terms, including ‘biosimilar’ and ‘inter-*
 18 *changeable’, and clarification regarding the use*
 19 *of interchangeable biosimilar biological products;*

20 “(B) *information related to development*
 21 *programs for biological products, including bio-*
 22 *similar biological products and interchangeable*
 23 *biosimilar biological products and relevant clin-*
 24 *ical considerations for prescribers, which may*
 25 *include, as appropriate and applicable, informa-*

1 *tion related to the comparability of such biological*
2 *cal products;*

3 *“(C) an explanation of the process for re-*
4 *porting adverse events for biological products, in-*
5 *cluding biosimilar biological products and inter-*
6 *changeable biosimilar biological products; and*

7 *“(D) an explanation of the relationship be-*
8 *tween biosimilar biological products and inter-*
9 *changeable biosimilar biological products li-*
10 *censed under section 351(k) and reference prod-*
11 *ucts (as defined in section 351(i)), including the*
12 *standards for review and licensing of each such*
13 *type of biological product.*

14 *“(3) FORMAT.—The educational materials pro-*
15 *vided under paragraph (1) may be—*

16 *“(A) in formats such as webinars, con-*
17 *tinuing medical education modules, videos, fact*
18 *sheets, infographics, stakeholder toolkits, or other*
19 *formats as appropriate and applicable; and*

20 *“(B) tailored for the unique needs of health*
21 *care providers, patients, caregivers, and other*
22 *audiences, as the Secretary determines appro-*
23 *priate.*

1 “(4) *OTHER INFORMATION.*—*In addition to the*
 2 *information described in paragraph (2), the Secretary*
 3 *shall continue to publish the following information:*

4 “(A) *The action package of each biological*
 5 *product licensed under subsection (a) or (k).*

6 “(B) *The summary review of each biological*
 7 *product licensed under subsection (a) or (k).*

8 “(5) *CONFIDENTIAL AND TRADE SECRET INFOR-*
 9 *MATION.*—*This subsection does not authorize the dis-*
 10 *closure of any trade secret, confidential commercial or*
 11 *financial information, or other matter described in*
 12 *section 552(b) of title 5.*

13 “(b) *CONTINUING EDUCATION.*—*The Secretary shall*
 14 *advance education and awareness among health care pro-*
 15 *viders regarding biological products, including biosimilar*
 16 *biological products and interchangeable biosimilar biologi-*
 17 *cal products, as appropriate, including by developing or*
 18 *improving continuing medical education programs that ad-*
 19 *vance the education of such providers on the prescribing of,*
 20 *and relevant clinical considerations with respect to, biologi-*
 21 *cal products, including biosimilar biological products and*
 22 *interchangeable biosimilar biological products.”.*

23 **SEC. 207. BIOLOGICAL PRODUCT INNOVATION.**

24 *Section 351(j) of the Public Health Service Act (42*
 25 *U.S.C. 262(j)) is amended—*

1 (1) *by striking “except that a product” and in-*
 2 *serting “except that—*
 3 *“(1) a product”;*
 4 (2) *by striking “Act.” and inserting “Act; and”;*
 5 *and*
 6 (3) *by adding at the end the following:*
 7 “(2) *no requirement under such Act regarding*
 8 *an official compendium (as defined in section 201(j)*
 9 *of such Act), or other reference in such Act to an offi-*
 10 *cial compendium (as so defined), shall apply with re-*
 11 *spect to a biological product subject to regulation*
 12 *under this section.”.*

13 **SEC. 208. CLARIFYING THE MEANING OF NEW CHEMICAL**
 14 **ENTITY.**

15 (a) *IN GENERAL.*—Chapter V of the Federal Food,
 16 *Drug, and Cosmetic Act is amended—*

17 (1) *in section 505 (21 U.S.C. 355)—*
 18 (A) *in subsection (c)(3)(E), by striking “ac-*
 19 *tive ingredient (including any ester or salt of the*
 20 *active ingredient)” each place it appears and in-*
 21 *serting “active moiety (as defined by the Sec-*
 22 *retary in section 314.3 of title 21, Code of Fed-*
 23 *eral Regulations (or any successor regula-*
 24 *tions))”;*

1 (B) in subsection (j)(5)(F), by striking “ac-
 2 tive ingredient (including any ester or salt of the
 3 active ingredient)” each place it appears and in-
 4 serting “active moiety (as defined by the Sec-
 5 retary in section 314.3 of title 21, Code of Fed-
 6 eral Regulations (or any successor regula-
 7 tions))”;

8 (C) in subsection (l)(2)(A)—

9 (i) by amending clause (i) to read as
 10 follows:

11 “(i) not later than 30 days after the date of
 12 approval of such applications—

13 “(I) for a drug, no active moiety (as
 14 defined by the Secretary in section 314.3 of
 15 title 21, Code of Federal Regulations (or
 16 any successor regulations)) of which has
 17 been approved in any other application
 18 under this section; or

19 “(II) for a biological product, no active
 20 ingredient of which has been approved in
 21 any other application under section 351 of
 22 the Public Health Service Act; and”;

23 (ii) in clause (ii), by inserting “or bio-
 24 logical product” before the period;

1 (D) by amending subsection (s) to read as
 2 follows:

3 “(s) *REFERRAL TO ADVISORY COMMITTEE.*—The Sec-
 4 retary shall—

5 “(1) refer a drug or biological product to a Food
 6 and Drug Administration advisory committee for re-
 7 view at a meeting of such advisory committee prior
 8 to the approval of such drug or biological if it is—

9 “(A) a drug, no active moiety (as defined
 10 by the Secretary in section 314.3 of title 21,
 11 Code of Federal Regulations (or any successor
 12 regulations)) of which has been approved in any
 13 other application under this section; or

14 “(B) a biological product, no active ingre-
 15 dient of which has been approved in any other
 16 application under section 351 of the Public
 17 Health Service Act; or

18 “(2) if the Secretary does not refer a drug or bio-
 19 logical product described in paragraph (1) to a Food
 20 and Drug Administration advisory committee prior
 21 to such approval, provide in the action letter on the
 22 application for the drug or biological product a sum-
 23 mary of the reasons why the Secretary did not refer
 24 the drug or biological product to an advisory com-
 25 mittee prior to approval.”; and

1 (E) in subsection (u)(1), in the matter pre-
 2 ceding subparagraph (A)—

3 (i) by striking “active ingredient (in-
 4 cluding any ester or salt of the active ingre-
 5 dient)” and inserting “active moiety (as de-
 6 fined by the Secretary in section 314.3 of
 7 title 21, Code of Federal Regulations (or
 8 any successor regulations))”; and

9 (ii) by striking “same active ingre-
 10 dient” and inserting “same active moiety”;

11 (2) in section 512(c)(2)(F) (21 U.S.C.
 12 360b(c)(2)(F)), by striking “active ingredient (includ-
 13 ing any ester or salt of the active ingredient)” each
 14 place it appears and inserting “active moiety (as de-
 15 fined by the Secretary in section 314.3 of title 21,
 16 Code of Federal Regulations (or any successor regula-
 17 tions))”;

18 (3) in section 524(a)(4) (21 U.S.C. 360n(a)(4)),
 19 by amending subparagraph (C) to read as follows:

20 “(C) is for—

21 “(i) a human drug, no active moiety
 22 (as defined by the Secretary in section
 23 314.3 of title 21, Code of Federal Regula-
 24 tions (or any successor regulations)) of

1 *which has been approved in any other ap-*
 2 *plication under section 505(b)(1); or*

3 *“(ii) a biological product, no active in-*
 4 *gredient of which has been approved in any*
 5 *other application under section 351 of the*
 6 *Public Health Service Act.”;*

7 *(4) in section 529(a)(4) (21 U.S.C. 21 U.S.C.*
 8 *360ff(a)(4)), by striking subparagraphs (A) and (B)*
 9 *and inserting the following:*

10 *“(A) is for a drug or biological product that*
 11 *is for the prevention or treatment of a rare pedi-*
 12 *atric disease;*

13 *“(B)(i) is for such a drug—*

14 *“(I) that contains no active moiety (as*
 15 *defined by the Secretary in section 314.3 of*
 16 *title 21, Code of Federal Regulations (or*
 17 *any successor regulations)) that has been*
 18 *previously approved in any other applica-*
 19 *tion under subsection (b)(1), (b)(2), or (j) of*
 20 *section 505; and*

21 *“(II) that is the subject of an applica-*
 22 *tion submitted under section 505(b)(1); or*

23 *“(ii) or is for such a biological product—*

24 *“(I) that contains no active ingredient*
 25 *that has been previously approved in any*

1 *other application under section 351(a) or*
 2 *351(k) of the Public Health Service Act;*
 3 *and*

4 *“(II) that is the subject of an applica-*
 5 *tion submitted under section 351(a) of the*
 6 *Public Health Service Act;”*; and

7 *(5) in section 565A(a)(4) (21 U.S.C. 360bbb-*
 8 *4a(a)(4)), by amending subparagraph (D) to read as*
 9 *follows:*

10 *“(D) is for—*

11 *“(i) a human drug, no active moiety*
 12 *(as defined by the Secretary in section*
 13 *314.3 of title 21, Code of Federal Regula-*
 14 *tions (or any successor regulations)) of*
 15 *which has been approved in any other ap-*
 16 *plication under section 505(b)(1); or*

17 *“(ii) a biological product, no active in-*
 18 *gredient of which has been approved in any*
 19 *other application under section 351 of the*
 20 *Public Health Service Act.”.*

21 *(b) TECHNICAL CORRECTIONS.—Chapter V of the Fed-*
 22 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq)*
 23 *is amended—*

24 *(1) in section 505 (21 U.S.C. 355)—*

1 (A) in subsection (c)(3)(E), by repealing
2 clause (i); and

3 (B) in subsection (j)(5)(F), by repealing
4 clause (i); and

5 (2) in section 505A(c)(1)(A)(i)(II) (21 U.S.C.
6 355a(c)(1)(A)(i)), by striking “(c)(3)(D)” and insert-
7 ing “(c)(3)(E)”.

8 **SEC. 209. STREAMLINING THE TRANSITION OF BIOLOGICAL**
9 **PRODUCTS.**

10 Section 7002(e)(4) of the *Biologics Price Competition*
11 *and Innovation Act of 2009* (Public Law 111–148) is
12 amended by adding at the end the following: “With respect
13 to an application for a biological product submitted under
14 section 505(b) of the *Federal Food, Drug, and Cosmetic Act*
15 (21 U.S.C. 355(b)) with a filing date that is not later than
16 September 23, 2019, and that does not receive final ap-
17 proval on or before March 23, 2020, such application shall
18 be deemed to be withdrawn and the Secretary shall refund
19 the fee paid under section 736(a)(1)(B) of the *Federal Food,*
20 *Drug, and Cosmetic Act* (21 U.S.C. 379h(a)(1)(B)). Not-
21 withstanding any such withdrawal of the drug application,
22 the Secretary shall consider any previously conducted sci-
23 entific review and accelerate review of any such subsequent
24 application with respect to such biological product under
25 section 351 of the *Public Health Service Act* (42 U.S.C.

1 262). *The Secretary shall provide additional assistance to*
 2 *the sponsor or manufacturer of such application.”.*

3 **SEC. 210. ORPHAN DRUG CLARIFICATION.**

4 *Section 527(c) of the Federal Food, Drug, and Cos-*
 5 *metic Act (21 U.S.C. 360cc(c)) is amended by adding at*
 6 *the end the following:*

7 “(3) *APPLICABILITY.*—*This subsection applies to*
 8 *any drug designated under section 526 for which an*
 9 *application was approved under section 505 of this*
 10 *Act or licensed under section 351 of the Public Health*
 11 *Service Act after the date of enactment of the FDA*
 12 *Reauthorization Act of 2017, regardless of the date of*
 13 *on which such drug was designated under section*
 14 *526.”.*

15 **SEC. 211. PROMPT APPROVAL OF DRUGS RELATED TO SAFE-**
 16 **TY INFORMATION.**

17 *Section 505 of the Federal Food, Drug, and Cosmetic*
 18 *Act (21 U.S.C. 355) is amended by adding at the end the*
 19 *following:*

20 “(z) *PROMPT APPROVAL OF DRUGS WHEN SAFETY IN-*
 21 *FORMATION IS ADDED TO LABELING.*—

22 “(1) *GENERAL RULE.*—*A drug for which an ap-*
 23 *plication has been submitted or approved under sub-*
 24 *section (b)(2) or (j) shall not be considered ineligible*
 25 *for approval under this section or misbranded under*

1 *section 502 on the basis that the labeling of the drug*
 2 *omits safety information, including contraindica-*
 3 *tions, warnings, precautions, dosing, administration,*
 4 *or other information pertaining to safety, when the*
 5 *omitted safety information is protected by exclusivity*
 6 *under clause (iii) or (iv) of subsection (j)(5)(F),*
 7 *clause (iii) or (iv) of subsection (c)(3)(E), or section*
 8 *527(a), or by an extension of such exclusivity under*
 9 *section 505A or 505E.*

10 *“(2) LABELING.—Notwithstanding clauses (iii)*
 11 *and (iv) of subsection (j)(5)(F), clauses (iii) and (iv)*
 12 *of subsection (c)(3)(E), or section 527, the Secretary*
 13 *shall require that the labeling of a drug approved*
 14 *pursuant to an application submitted under sub-*
 15 *section (b)(2) or (j) that omits safety information de-*
 16 *scribed in paragraph (1) include a statement of any*
 17 *appropriate safety information that the Secretary*
 18 *considers necessary to assure safe use.*

19 *“(3) AVAILABILITY AND SCOPE OF EXCLU-*
 20 *SIVITY.—This subsection does not affect—*

21 *“(A) the availability or scope of exclusivity*
 22 *or an extension of exclusivity described in sub-*
 23 *paragraph (A) or (B) of section 505A(o)(3);*

24 *“(B) the question of the eligibility for ap-*
 25 *proval under this section of any application de-*

scribed in subsection (b)(2) or (j) that omits any other aspect of labeling protected by exclusivity under—

“(i) clause (iii) or (iv) of subsection (j)(5)(F);

“(ii) clause (iii) or (iv) of subsection (c)(3)(E); or

“(iii) section 527(a); or

“(C) except as expressly provided in paragraphs (1) and (2), the operation of this section or section 527.”.

SEC. 212. CONDITIONS OF USE FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 351(k)(2)(A)(iii) of the Public Health Service Act (42 U.S.C. 262(k)(2)(A)(iii)) is amended—

(1) in subclause (I), by striking “; and” and inserting a semicolon;

(2) in subclause (II), by striking the period and inserting “; and”; and

(3) by adding at the end the following:

“(III) may include information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological

1 *product have been previously approved*
 2 *for the reference product.”.*

3 **SEC. 213. MODERNIZING THE LABELING OF CERTAIN GE-**
 4 **NERIC DRUGS.**

5 *Chapter V of the Federal Food, Drug, and Cosmetic*
 6 *Act (21 U.S.C. 351 et seq.) is amended by inserting after*
 7 *section 503C the following:*

8 **“SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN**
 9 **DRUGS.**

10 *“(a) DEFINITIONS.—For purposes of this section:*

11 *“(1) The term ‘covered drug’ means a drug ap-*
 12 *proved under section 505(c)—*

13 *“(A) for which there are no unexpired pat-*
 14 *ents included in the list under section 505(j)(7)*
 15 *and no unexpired period of exclusivity;*

16 *“(B) for which the approval of the applica-*
 17 *tion has been withdrawn for reasons other than*
 18 *safety or effectiveness; and*

19 *“(C) for which, with respect to the label-*
 20 *ing—*

21 *“(i) new scientific evidence is available*
 22 *regarding the conditions of use of the drug;*

23 *“(ii) there is a relevant accepted use in*
 24 *clinical practice that is not reflected in the*
 25 *approved labeling; or*

1 “(iii) the labeling of such drug does not
2 reflect current legal and regulatory require-
3 ments.

4 “(2) The term ‘period of exclusivity’, with respect
5 to a drug approved under section 505(c), means any
6 period of exclusivity under clause (ii), (iii), or (iv) of
7 section 505(c)(3)(E), clause (ii), (iii), or (iv) of sec-
8 tion 505(j)(5)(F), or section 505A, 505E, or 527.

9 “(3) The term ‘generic version’ means a drug ap-
10 proved under section 505(j) whose reference drug is a
11 covered drug.

12 “(4) The term ‘relevant accepted use’ means a
13 use for a drug in clinical practice that is supported
14 by scientific evidence that appears to the Secretary to
15 meet the standards for approval under section 505.

16 “(5) The term ‘selected drug’ means a covered
17 drug for which the Secretary has determined through
18 the process under subsection (c) that the labeling
19 should be changed.

20 “(b) IDENTIFICATION OF COVERED DRUGS.—The Sec-
21 retary may identify covered drugs for which labeling up-
22 dates would provide a public health benefit. To assist in
23 identifying covered drugs, the Secretary may do one or both
24 of the following:

1 “(1) *Enter into cooperative agreements or con-*
 2 *tracts with public or private entities to review the*
 3 *available scientific evidence concerning such drugs.*

4 “(2) *Seek public input concerning such drugs,*
 5 *including input on whether there is a relevant accept-*
 6 *ed use in clinical practice that is not reflected in the*
 7 *approved labeling of such drugs or whether new sci-*
 8 *entific evidence is available regarding the conditions*
 9 *of use for such drug, by—*

10 “(A) *holding one or more public meetings;*

11 “(B) *opening a public docket for the sub-*
 12 *mission of public comments; or*

13 “(C) *other means, as the Secretary deter-*
 14 *mines appropriate.*

15 “(c) *SELECTION OF DRUGS FOR UPDATING.—If the*
 16 *Secretary determines, with respect to a covered drug, that*
 17 *the available scientific evidence meets the standards under*
 18 *section 505 for adding or modifying information to the la-*
 19 *beling or providing supplemental information to the label-*
 20 *ing regarding the use of the covered drug, the Secretary may*
 21 *initiate the process under subsection (d).*

22 “(d) *INITIATION OF THE PROCESS OF UPDATING.—If*
 23 *the Secretary determines that labeling changes are appro-*
 24 *priate for a selected drug pursuant to subsection (c), the*

1 *Secretary shall provide notice to the holders of approved*
2 *applications for a generic version of such drug that—*

3 “(1) *summarizes the findings supporting the de-*
4 *termination of the Secretary that the available sci-*
5 *entific evidence meets the standards under section 505*
6 *for adding or modifying information or providing*
7 *supplemental information to the labeling of the cov-*
8 *ered drug pursuant to subsection (c);*

9 “(2) *provides a clear statement regarding the ad-*
10 *ditional, modified, or supplemental information for*
11 *such labeling, according to the determination by the*
12 *Secretary (including, as applicable, modifications to*
13 *add the relevant accepted use to the labeling of the*
14 *drug as an additional indication for the drug); and*

15 “(3) *states whether the statement under para-*
16 *graph (2) applies to the selected drug as a class of*
17 *covered drugs or only to a specific drug product.*

18 “(e) *RESPONSE TO NOTIFICATION.—Within 30 days of*
19 *receipt of notification provided by the Secretary pursuant*
20 *to subsection (d), the holder of an approved application for*
21 *a generic version of the selected drug shall—*

22 “(1) *agree to change the approved labeling to re-*
23 *flect the additional, modified, or supplemental infor-*
24 *mation the Secretary has determined to be appro-*
25 *priate; or*

1 “(2) *notify the Secretary that the holder of the*
2 *approved application does not believe that the re-*
3 *quested labeling changes are warranted and submit a*
4 *statement detailing the reasons why such changes are*
5 *not warranted.*

6 “(f) *REVIEW OF APPLICATION HOLDER’S RE-*
7 *SPONSE.—*

8 “(1) *IN GENERAL.—Upon receipt of the applica-*
9 *tion holder’s response, the Secretary shall promptly*
10 *review each statement received under subsection (e)(2)*
11 *and determine which labeling changes pursuant to the*
12 *Secretary’s notice under subsection (d) are appro-*
13 *priate, if any. If the Secretary disagrees with the rea-*
14 *sons why such labeling changes are not warranted, the*
15 *Secretary shall provide opportunity for discussions*
16 *with the application holders to reach agreement on*
17 *whether the labeling for the covered drug should be*
18 *updated to reflect current scientific evidence, and if*
19 *so, the content of such labeling changes.*

20 “(2) *CHANGES TO LABELING.—After considering*
21 *all responses from the holder of an approved applica-*
22 *tion under paragraph (1) or (2) of subsection (e), and*
23 *any discussion under paragraph (1), the Secretary*
24 *may order such holder to make the labeling changes*

1 *the Secretary determines are appropriate. Such holder*
 2 *of an approved application shall—*

3 *“(A) update its paper labeling for the drug*
 4 *at the next printing of that labeling;*

5 *“(B) update any electronic labeling for the*
 6 *drug within 30 days; and*

7 *“(C) submit the revised labeling through the*
 8 *form, ‘Supplement—Changes Being Effected’.*

9 *“(g) VIOLATION.—If the holder of an approved appli-*
 10 *cation for the generic version of the selected drug does not*
 11 *comply with the requirements of subsection (f)(2), such ge-*
 12 *neric version of the selected drug shall be deemed to be mis-*
 13 *branded under section 502.*

14 *“(h) LIMITATIONS; GENERIC DRUGS.—*

15 *“(1) IN GENERAL.—With respect to any labeling*
 16 *change required under this section, the generic version*
 17 *shall be deemed to have the same conditions of use*
 18 *and the same labeling as a reference drug for pur-*
 19 *poses of clauses (i) and (v) of section 505(j)(2)(A).*
 20 *Any labeling change so required shall not have any*
 21 *legal effect for the applicant that is different than the*
 22 *legal effect that would have resulted if a supplemental*
 23 *application had been submitted and approved to con-*
 24 *form the labeling of the generic version to a change*
 25 *in the labeling of the reference drug.*

1 “(2) *SUPPLEMENTAL APPLICATIONS.*—Changes to
2 *labeling made in accordance with this paragraph*
3 *shall not be eligible for an exclusivity period under*
4 *this Act.*

5 “(i) *DRUG PRODUCT CLASSES.*—In the case of a se-
6 *lected drug for which the labeling changes ordered by the*
7 *Secretary under subsection (d)(2) are required for a class*
8 *of covered drugs, such labeling changes shall be made for*
9 *generic versions of such drug in that class.*

10 “(j) *RULES OF CONSTRUCTION.*—

11 “(1) *APPROVAL STANDARDS.*—This section shall
12 *not be construed as altering the applicability of the*
13 *standards for approval of an application under sec-*
14 *tion 505. No order shall be issued under this sub-*
15 *section unless the evidence supporting the changed la-*
16 *beling meets the standards for approval applicable to*
17 *any change to labeling under section 505.*

18 “(2) *REMOVAL OF INFORMATION.*—Nothing in
19 *this section shall be construed to give the Secretary*
20 *additional authority to remove approved indications*
21 *for drugs, other than the authority described in this*
22 *section.*

23 “(k) *REPORTS.*—Not later than 4 years after the date
24 *of the enactment of the Lower Health Care Costs Act and*
25 *every 4 years thereafter, the Secretary shall prepare and*

1 *submit to the Committee on Health, Education, Labor, and*
 2 *Pensions of the Senate and the Committee on Energy and*
 3 *Commerce of the House of Representatives, a report that—*

4 *“(1) describes the actions of the Secretary under*
 5 *this section, including—*

6 *“(A) the number of covered drugs and de-*
 7 *scription of the types of drugs the Secretary has*
 8 *selected for labeling changes and the rationale for*
 9 *such recommended changes; and*

10 *“(B) the number of times the Secretary en-*
 11 *tered into discussions concerning a disagreement*
 12 *with an application holder or holders and a*
 13 *summary of the decision regarding a labeling*
 14 *change, if any; and*

15 *“(2) includes any recommendations of the Sec-*
 16 *retary for modifying the program under this sec-*
 17 *tion.”.*

18 **SEC. 214. ACTIONS FOR DELAYS OF GENERIC DRUGS AND**

19 **BIOSIMILAR BIOLOGICAL PRODUCTS.**

20 *(a) DEFINITIONS.—In this section—*

21 *(1) the term “commercially reasonable, market-*
 22 *based terms” means—*

23 *(A) a nondiscriminatory price for the sale*
 24 *of the covered product at or below, but not great-*
 25 *er than, the most recent wholesale acquisition*

1 *cost for the drug, as defined in section*
 2 *1847A(c)(6)(B) of the Social Security Act (42*
 3 *U.S.C. 1395w–3a(c)(6)(B));*

4 *(B) a schedule for delivery that results in*
 5 *the transfer of the covered product to the eligible*
 6 *product developer consistent with the timing*
 7 *under subsection (b)(2)(A)(iv); and*

8 *(C) no additional conditions are imposed*
 9 *on the sale of the covered product;*

10 *(2) the term “covered product”—*

11 *(A) means—*

12 *(i) any drug approved under sub-*
 13 *section (c) or (j) of section 505 of the Fed-*
 14 *eral Food, Drug, and Cosmetic Act (21*
 15 *U.S.C. 355) or biological product licensed*
 16 *under subsection (a) or (k) of section 351 of*
 17 *the Public Health Service Act (42 U.S.C.*
 18 *262);*

19 *(ii) any combination of a drug or bio-*
 20 *logical product described in clause (i); or*

21 *(iii) when reasonably necessary to sup-*
 22 *port approval of an application under sec-*
 23 *tion 505 of the Federal Food, Drug, and*
 24 *Cosmetic Act (21 U.S.C. 355), or section*
 25 *351 of the Public Health Service Act (42*

1 *U.S.C. 262), as applicable, or otherwise*
2 *meet the requirements for approval under*
3 *either such section, any product, including*
4 *any device, that is marketed or intended for*
5 *use with such a drug or biological product;*
6 *and*

7 *(B) does not include any drug or biological*
8 *product that appears on the drug shortage list in*
9 *effect under section 506E of the Federal Food,*
10 *Drug, and Cosmetic Act (21 U.S.C. 356e), un-*
11 *less—*

12 *(i) the drug or biological product has*
13 *been on the drug shortage list in effect*
14 *under such section 506E continuously for*
15 *more than 6 months; or*

16 *(ii) the Secretary determines that in-*
17 *clusion of the drug or biological product as*
18 *a covered product is likely to contribute to*
19 *alleviating or preventing a shortage.*

20 *(3) the term “device” has the meaning given the*
21 *term in section 201 of the Federal Food, Drug, and*
22 *Cosmetic Act (21 U.S.C. 321);*

23 *(4) the term “eligible product developer” means*
24 *a person that seeks to develop a product for approval*
25 *pursuant to an application for approval under sub-*

1 *section (b)(2) or (j) of section 505 of the Federal*
2 *Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for*
3 *licensing pursuant to an application under section*
4 *351(k) of the Public Health Service Act (42 U.S.C.*
5 *262(k));*

6 *(5) the term “license holder” means the holder of*
7 *an application approved under subsection (c) or (j) of*
8 *section 505 of the Federal Food, Drug, and Cosmetic*
9 *Act (21 U.S.C. 355) or the holder of a license under*
10 *subsection (a) or (k) of section 351 of the Public*
11 *Health Service Act (42 U.S.C. 262) for a covered*
12 *product;*

13 *(6) the term “REMS” means a risk evaluation*
14 *and mitigation strategy under section 505–1 of the*
15 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
16 *355–1);*

17 *(7) the term “REMS with ETASU” means a*
18 *REMS that contains elements to assure safe use under*
19 *section 505–1(f) of the Federal Food, Drug, and Cos-*
20 *metic Act (21 U.S.C. 355–1(f));*

21 *(8) the term “Secretary” means the Secretary of*
22 *Health and Human Services;*

23 *(9) the term “single, shared system of elements to*
24 *assure safe use” means a single, shared system of ele-*
25 *ments to assure safe use under section 505–1(f) of the*

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)); and

(10) the term “sufficient quantities” means an amount of a covered product that the eligible product developer determines allows it to—

(A) conduct testing to support an application under—

(i) subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

(ii) section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(B) fulfill any regulatory requirements relating to approval of such an application.

(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—

(1) IN GENERAL.—An eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this subsection in an appropriate district court of the United States alleging that the license holder has declined to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

(2) ELEMENTS.—

1 (A) *IN GENERAL.*—*To prevail in a civil ac-*
2 *tion brought under paragraph (1), an eligible*
3 *product developer shall prove, by a preponder-*
4 *ance of the evidence—*

5 (i) *that—*

6 (I) *the covered product is not sub-*
7 *ject to a REMS with ETASU; or*

8 (II) *if the covered product is sub-*
9 *ject to a REMS with ETASU—*

10 (aa) *the eligible product de-*
11 *veloper has obtained a covered*
12 *product authorization from the*
13 *Secretary in accordance with sub-*
14 *paragraph (B); and*

15 (bb) *the eligible product de-*
16 *veloper has provided a copy of the*
17 *covered product authorization to*
18 *the license holder;*

19 (ii) *that, as of the date on which the*
20 *civil action is filed, the product developer*
21 *has not obtained sufficient quantities of the*
22 *covered product on commercially reasonable,*
23 *market-based terms;*

24 (iii) *that the eligible product developer*
25 *has submitted a written request to purchase*

1 *sufficient quantities of the covered product*
2 *to the license holder, and such request—*

3 *(I) was sent to a named corporate*
4 *officer of the license holder;*

5 *(II) was made by certified or reg-*
6 *istered mail with return receipt re-*
7 *quested;*

8 *(III) specified an individual as*
9 *the point of contact for the license*
10 *holder to direct communications re-*
11 *lated to the sale of the covered product*
12 *to the eligible product developer and a*
13 *means for electronic and written com-*
14 *munications with that individual; and*

15 *(IV) specified an address to which*
16 *the covered product was to be shipped*
17 *upon reaching an agreement to trans-*
18 *fer the covered product; and*

19 *(iv) that the license holder has not de-*
20 *livered to the eligible product developer suf-*
21 *ficient quantities of the covered product on*
22 *commercially reasonable, market-based*
23 *terms—*

24 *(I) for a covered product that is*
25 *not subject to a REMS with ETASU,*

1 *by the date that is 31 days after the*
 2 *date on which the license holder re-*
 3 *ceived the request for the covered prod-*
 4 *uct; and*

5 *(II) for a covered product that is*
 6 *subject to a REMS with ETASU, by*
 7 *31 days after the later of—*

8 *(aa) the date on which the li-*
 9 *cence holder received the request*
 10 *for the covered product; or*

11 *(bb) the date on which the li-*
 12 *cence holder received a copy of the*
 13 *covered product authorization*
 14 *issued by the Secretary in accord-*
 15 *ance with subparagraph (B).*

16 *(B) AUTHORIZATION FOR COVERED PROD-*
 17 *UCT SUBJECT TO A REMS WITH ETASU.—*

18 *(i) REQUEST.—An eligible product de-*
 19 *veloper may submit to the Secretary a writ-*
 20 *ten request for the eligible product developer*
 21 *to be authorized to obtain sufficient quan-*
 22 *tities of an individual covered product sub-*
 23 *ject to a REMS with ETASU.*

24 *(ii) AUTHORIZATION.—Not later than*
 25 *120 days after the date on which a request*

1 *under clause (i) is received, the Secretary*
2 *shall, by written notice, authorize the eligi-*
3 *ble product developer to obtain sufficient*
4 *quantities of an individual covered product*
5 *subject to a REMS with ETASU for pur-*
6 *poses of—*

7 *(I) development and testing that*
8 *does not involve human clinical trials,*
9 *if the eligible product developer has*
10 *agreed to comply with any conditions*
11 *the Secretary determines necessary; or*

12 *(II) development and testing that*
13 *involves human clinical trials, if the*
14 *eligible product developer has—*

15 *(aa)(AA) submitted protocols,*
16 *informed consent documents, and*
17 *informational materials for test-*
18 *ing that include protections that*
19 *provide safety protections com-*
20 *parable to those provided by the*
21 *REMS for the covered product; or*

22 *(BB) otherwise satisfied the*
23 *Secretary that such protections*
24 *will be provided; and*

1 (bb) met any other require-
2 ments the Secretary may estab-
3 lish.

4 (iii) NOTICE.—A covered product au-
5 thorization issued under this subparagraph
6 shall state that the provision of the covered
7 product by the license holder under the
8 terms of the authorization will not be a vio-
9 lation of the REMS for the covered product.

10 (3) AFFIRMATIVE DEFENSE.—In a civil action
11 brought under paragraph (1), it shall be an affirma-
12 tive defense, on which the defendant has the burden
13 of persuasion by a preponderance of the evidence—

14 (A) that, on the date on which the eligible
15 product developer requested to purchase sufficient
16 quantities of the covered product from the license
17 holder—

18 (i) neither the license holder nor any of
19 its agents, wholesalers, or distributors was
20 engaged in the manufacturing or commer-
21 cial marketing of the covered product; and

22 (ii) neither the license holder nor any
23 of its agents, wholesalers, or distributors
24 otherwise had access to inventory of the cov-
25 ered product to supply to the eligible prod-

uct developer on commercially reasonable,
market-based terms;

(B) that—

(i) the license holder sells the covered
product through agents, distributors, or
wholesalers;

(ii) the license holder has placed no re-
strictions, explicit or implicit, on its agents,
distributors, or wholesalers to sell covered
products to eligible product developers; and

(iii) the covered product can be pur-
chased by the eligible product developer in
sufficient quantities on commercially rea-
sonable, market-based terms from the
agents, distributors, or wholesalers of the li-
cense holder; or

(C) that the license holder made an offer to
the individual specified pursuant to paragraph
(2)(A)(iii)(III), by a means of communication
(electronic, written, or both) specified pursuant
to such paragraph, to sell sufficient quantities of
the covered product to the eligible product devel-
oper at commercially reasonable 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 which
 4 the license holder received the request for the
 5 covered product, and the eligible product de-
 6 veloper did not accept such offer by the date
 7 that is 7 days after the date on which the
 8 eligible product developer received such offer
 9 from the license holder; or

10 (ii) for a covered product that is sub-
 11 ject to a REMS with ETASU, by the date
 12 that is 20 days after the date on which the
 13 license holder received the request for the
 14 covered product, and the eligible product de-
 15 veloper did not accept such offer by the date
 16 that is 10 days after the date on which the
 17 eligible product developer received such offer
 18 from the license holder.

19 (4) *REMEDIES.*—

20 (A) *IN GENERAL.*—If an eligible product de-
 21 veloper prevails in a civil action brought under
 22 paragraph (1), the court shall—

23 (i) order the license holder to provide
 24 to the eligible product developer without
 25 delay sufficient quantities of the covered

1 *product on commercially reasonable, mar-*
2 *ket-based terms;*

3 *(ii) award to the eligible product devel-*
4 *oper reasonable attorney's fees and costs of*
5 *the civil action; and*

6 *(iii) award to the eligible product de-*
7 *veloper a monetary amount sufficient to*
8 *deter the license holder from failing to pro-*
9 *vide eligible product developers with suffi-*
10 *cient quantities of a covered product on*
11 *commercially reasonable, market-based*
12 *terms, if the court finds, by a preponder-*
13 *ance of the evidence—*

14 *(I) that the license holder delayed*
15 *providing sufficient quantities of the*
16 *covered product to the eligible product*
17 *developer without a legitimate business*
18 *justification; or*

19 *(II) that the license holder failed*
20 *to comply with an order issued under*
21 *clause (i).*

22 *(B) MAXIMUM MONETARY AMOUNT.—A*
23 *monetary amount awarded under subparagraph*
24 *(A)(iii) shall not be greater than the revenue that*

1 *the license holder earned on the covered product*
2 *during the period—*

3 *(i) beginning on—*

4 *(I) for a covered product that is*
5 *not subject to a REMS with ETASU,*
6 *the date that is 31 days after the date*
7 *on which the license holder received the*
8 *request; or*

9 *(II) for a covered product that is*
10 *subject to a REMS with ETASU, the*
11 *date that is 31 days after the later of—*

12 *(aa) the date on which the li-*
13 *cense holder received the request;*
14 *or*

15 *(bb) the date on which the li-*
16 *cense holder received a copy of the*
17 *covered product authorization*
18 *issued by the Secretary in accord-*
19 *ance with paragraph (2)(B); and*

20 *(ii) ending on the date on which the el-*
21 *igible product developer received sufficient*
22 *quantities of the covered product.*

23 *(C) AVOIDANCE OF DELAY.—The court may*
24 *issue an order under subparagraph (A)(i) before*
25 *conducting further proceedings that may be nec-*

1 *essary to determine whether the eligible product*
 2 *developer is entitled to an award under clause*
 3 *(ii) or (iii) of subparagraph (A), or the amount*
 4 *of any such award.*

5 *(c) LIMITATION OF LIABILITY.—A license holder for a*
 6 *covered product shall not be liable for any claim under Fed-*
 7 *eral, State, or local law arising out of the failure of an*
 8 *eligible product developer to follow adequate safeguards to*
 9 *assure safe use of the covered product during development*
 10 *or testing activities described in this section, including*
 11 *transportation, handling, use, or disposal of the covered*
 12 *product by the eligible product developer.*

13 *(d) NO VIOLATION OF REMS.—Section 505–1 of the*
 14 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1)*
 15 *is amended by adding at the end the following new sub-*
 16 *section:*

17 *“(l) PROVISION OF SAMPLES NOT A VIOLATION OF*
 18 *STRATEGY.—The provision of samples of a covered product*
 19 *to an eligible product developer (as those terms are defined*
 20 *in section 214(a) of the Lower Health Care Costs Act) shall*
 21 *not be considered a violation of the requirements of any risk*
 22 *evaluation and mitigation strategy that may be in place*
 23 *under this section for such drug.”.*

24 *(e) RULE OF CONSTRUCTION.—*

1 (1) *DEFINITION.*—*In this subsection, the term*
 2 *“antitrust laws”*—

3 *(A) has the meaning given the term in sub-*
 4 *section (a) of the first section of the Clayton Act*
 5 *(15 U.S.C. 12); and*

6 *(B) includes section 5 of the Federal Trade*
 7 *Commission Act (15 U.S.C. 45) to the extent that*
 8 *such section applies to unfair methods of com-*
 9 *petition.*

10 (2) *ANTITRUST LAWS.*—*Nothing in this section*
 11 *shall be construed to limit the operation of any provi-*
 12 *sion of the antitrust laws.*

13 (f) *REMS APPROVAL PROCESS FOR SUBSEQUENT FIL-*
 14 *ERS.*—*Section 505–1 of the Federal Food, Drug, and Cos-*
 15 *metic Act (21 U.S.C. 355–1), as amended by subsection (d),*
 16 *is further amended—*

17 *(1) in subsection (g)(4)(B)—*

18 *(A) in clause (i) by striking “or” after the*
 19 *semicolon;*

20 *(B) in clause (ii) by striking the period at*
 21 *the end and inserting “; or”; and*

22 *(C) by adding at the end the following:*

23 *“(iii) accommodate different, com-*
 24 *parable aspects of the elements to assure*
 25 *safe use for a drug that is the subject of an*

1 *application under section 505(j), and the*
 2 *applicable listed drug.”;*

3 *(2) in subsection (i)(1), by striking subpara-*
 4 *graph (C) and inserting the following:*

5 *“(C)(i) Elements to assure safe use, if re-*
 6 *quired under subsection (f) for the listed drug,*
 7 *which, subject to clause (ii), for a drug that is*
 8 *the subject of an application under section 505(j)*
 9 *may use—*

10 *“(I) a single, shared system with the*
 11 *listed drug under subsection (f); or*

12 *“(II) a different, comparable aspect of*
 13 *the elements to assure safe use under sub-*
 14 *section (f).*

15 *“(ii) The Secretary may require a drug that*
 16 *is the subject of an application under section*
 17 *505(j) and the listed drug to use a single, shared*
 18 *system under subsection (f), if the Secretary de-*
 19 *termines that no different, comparable aspect of*
 20 *the elements to assure safe use could satisfy the*
 21 *requirements of subsection (f).”;*

22 *(3) in subsection (i), by adding at the end the*
 23 *following:*

24 *“(3) SHARED REMS.—If the Secretary approves,*
 25 *in accordance with paragraph (1)(C)(i)(II), a dif-*

1 *ferent, comparable aspect of the elements to assure*
 2 *safe use under subsection (f) for a drug that is the*
 3 *subject of an abbreviated new drug application under*
 4 *section 505(j), the Secretary may require that such*
 5 *different comparable aspect of the elements to assure*
 6 *safe use can be used with respect to any other drug*
 7 *that is the subject of an application under section*
 8 *505(j) or 505(b) that references the same listed drug.”;*
 9 *and*

10 *(4) by adding at the end the following:*

11 *“(m) SEPARATE REMS.—When used in this section,*
 12 *the terms ‘different, comparable aspect of the elements to*
 13 *assure safe use’ or ‘different, comparable approved risk eval-*
 14 *uation and mitigation strategies’ means a risk evaluation*
 15 *and mitigation strategy for a drug that is the subject of*
 16 *an application under section 505(j) that uses different*
 17 *methods or operational means than the strategy required*
 18 *under subsection (a) for the applicable listed drug, or other*
 19 *application under section 505(j) with the same such listed*
 20 *drug, but achieves the same level of safety as such strategy.”.*

21 *(g) RULE OF CONSTRUCTION.—Nothing in this section,*
 22 *the amendments made by this section, or in section 505–*
 23 *1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 24 *355–1), shall be construed as—*

1 (1) *prohibiting a license holder from providing*
 2 *an eligible product developer access to a covered prod-*
 3 *uct in the absence of an authorization under this sec-*
 4 *tion; or*

5 (2) *in any way negating the applicability of a*
 6 *REMS with ETASU, as otherwise required under*
 7 *such section 505–1, with respect to such covered prod-*
 8 *uct.*

9 **SEC. 215. REDUCING THE PRICE OF PRESCRIPTION DRUGS.**

10 *Title III of the Public Health Service Act (42 U.S.C.*
 11 *241 et seq.) is amended by adding at the end the following:*

12 **“PART W—DRUG PRICE REPORTING; DRUG VALUE**
 13 **FUND**

14 **“SEC. 3990O. REPORTING ON JUSTIFICATION FOR DRUG**
 15 **PRICE INCREASES.**

16 “(a) *DEFINITIONS.—In this section:*

17 “(1) *MANUFACTURER.—The term ‘manufacturer’*
 18 *means the person—*

19 “(A) *that holds the application for a drug*
 20 *approved under section 505 of the Federal Food,*
 21 *Drug, and Cosmetic Act or the license issued*
 22 *under section 351 of this Act; or*

23 “(B) *who is responsible for setting the price*
 24 *for the drug.*

1 “(2) *QUALIFYING DRUG.*—*The term ‘qualifying*
 2 *drug’ means any drug that is approved under sub-*
 3 *section (c) or (j) of section 505 of the Federal Food,*
 4 *Drug, and Cosmetic Act or licensed under subsection*
 5 *(a) or (k) of section 351 of this Act—*

6 “(A) *that has a wholesale acquisition cost of*
 7 *\$100 or more per month supply, or per a course*
 8 *of treatment that lasts less than a month, and*
 9 *is—*

10 “(i)(I) *subject to section 503(b)(1) of*
 11 *the Federal Food, Drug, and Cosmetic Act;*
 12 *or*

13 “(II) *commonly administered by hos-*
 14 *pitals (as determined by the Secretary); and*

15 “(ii) *not designated by the Secretary*
 16 *as a vaccine; and*

17 “(B) *for which, during the previous cal-*
 18 *endar year, at least 1 dollar of the total amount*
 19 *of sales were for individuals enrolled under the*
 20 *Medicare program under title XVIII of the So-*
 21 *cial Security Act (42 U.S.C. 1395 et seq.) or*
 22 *under a State Medicaid plan under title XIX of*
 23 *such Act (42 U.S.C. 1396 et seq.) or under a*
 24 *waiver of such plan.*

1 “(3) *WHOLESALE ACQUISITION COST.*—*The term*
 2 *‘wholesale acquisition cost’ has the meaning given*
 3 *that term in section 1847A(c)(6)(B) of the Social Se-*
 4 *curity Act (42 U.S.C. 1395w–3a(c)(6)(B)).*

5 “(b) *REPORT.*—

6 “(1) *REPORT REQUIRED.*—*The manufacturer of*
 7 *a qualifying drug shall submit a report to the Sec-*
 8 *retary for each price increase of a qualifying drug*
 9 *that will result in an increase in the wholesale acqui-*
 10 *sition cost of that drug that is equal to—*

11 “(A) *10 percent or more over a 12-month*
 12 *period; or*

13 “(B) *25 percent or more over a 36-month*
 14 *period.*

15 “(2) *REPORT DEADLINE.*—*Each report described*
 16 *in paragraph (1) shall be submitted to the Secretary*
 17 *not later than 30 days prior to the planned effective*
 18 *date of such price increase.*

19 “(c) *CONTENTS.*—*A report under subsection (b) shall,*
 20 *at a minimum, include—*

21 “(1) *with respect to the qualifying drug—*

22 “(A) *the percentage by which the manufac-*
 23 *turer will raise the wholesale acquisition cost of*
 24 *the drug on the planned effective date of such*
 25 *price increase;*

1 “(B) a justification for, and description of,
2 each manufacturer’s price increase that will
3 occur during the 12-month period described in
4 subsection (b)(1)(A) or the 36-month period de-
5 scribed in subsection (b)(1)(B), as applicable;

6 “(C) the identity of the initial developer of
7 the drug;

8 “(D) a description of the history of the
9 manufacturer’s price increases for the drug since
10 the approval of the application for the drug
11 under section 505 of the Federal Food, Drug,
12 and Cosmetic Act or the issuance of the license
13 for the drug under section 351, or since the man-
14 ufacturer acquired such approved application or
15 license;

16 “(E) the current list price of the drug;

17 “(F) the total expenditures of the manufac-
18 turer on—

19 “(i) materials and manufacturing for
20 such drug; and

21 “(ii) acquiring patents and licensing
22 for such drug;

23 “(G) the percentage of total expenditures of
24 the manufacturer on research and development

1 *for such drug that was derived from Federal*
2 *funds;*

3 “(H) *the total expenditures of the manufac-*
4 *turer on research and development for such drug*
5 *that is used for—*

6 “(i) *basic and preclinical research;*

7 “(ii) *clinical research;*

8 “(iii) *new drug development;*

9 “(iv) *pursuing new or expanded indi-*
10 *cations for such drug through supplemental*
11 *applications under section 505 of the Fed-*
12 *eral Food, Drug, and Cosmetic Act or sec-*
13 *tion 351 of this Act; and*

14 “(v) *carrying out postmarket require-*
15 *ments related to such drug, including those*
16 *under section 505(o)(3) of the Federal Food,*
17 *Drug, and Cosmetic Act;*

18 “(I) *the total revenue and the net profit*
19 *generated from the qualifying drug for each cal-*
20 *endar year since the approval of the application*
21 *for the drug under section 505 of the Federal*
22 *Food, Drug, and Cosmetic Act or the issuance of*
23 *the license for the drug under section 351, or*
24 *since the manufacturer acquired such approved*
25 *application or license; and*

1 “(J) the total costs associated with mar-
2 keting and advertising for the qualifying drug;

3 “(2) with respect to the manufacturer—

4 “(A) the total revenue and the net profit of
5 the manufacturer—

6 “(i) for the 12-month period preceding
7 the date of the report, in the case of a report
8 based on an increase described in subsection
9 (b)(1)(A); or

10 “(ii) for the 36-month period preceding
11 the date of the report, in the case of a report
12 based on an increase described in subsection
13 (b)(1)(B);

14 “(B) all stock-based performance metrics
15 used by the manufacturer to determine executive
16 compensation—

17 “(i) for the 12-month period preceding
18 the date of the report, in the case of a report
19 based on an increase described in subsection
20 (b)(1)(A); or

21 “(ii) for the 36-month period preceding
22 the date of the report, in the case of a report
23 based on an increase described in subsection
24 (b)(1)(B); and

1 “(C) *any additional information the manu-*
 2 *facturer chooses to provide related to drug pric-*
 3 *ing decisions, such as total expenditures on—*

4 “(i) *drug research and development; or*

5 “(ii) *clinical trials on drugs that failed*
 6 *to receive approval by the Food and Drug*
 7 *Administration; and*

8 “(3) *such other related information as the Sec-*
 9 *retary considers appropriate, as specified through no-*
 10 *tice and comment rulemaking.*

11 “(d) *CIVIL PENALTY.—Any manufacturer of a quali-*
 12 *fying drug that fails to submit a report for the drug as*
 13 *required by this section shall be subject to a civil penalty*
 14 *of \$100,000 for each day on which the violation continues.*

15 “(e) *PUBLIC POSTING.—*

16 “(1) *IN GENERAL.—Subject to paragraph (3),*
 17 *not later than 30 days after the submission of a re-*
 18 *port under subsection (b), the Secretary shall post the*
 19 *report on the public website of the Department of*
 20 *Health and Human Services.*

21 “(2) *FORMAT.—In developing the format of such*
 22 *report for public posting, the Secretary shall consult*
 23 *stakeholders, including beneficiary groups, and shall*
 24 *seek feedback on the content and format from con-*
 25 *sumer advocates and readability experts to ensure*

1 *such public reports are user-friendly to the public and*
 2 *are written in plain language that consumers can*
 3 *readily understand.*

4 *“(3) TRADE SECRETS AND CONFIDENTIAL INFOR-*
 5 *MATION.—In carrying out this section the Secretary*
 6 *shall enforce current law concerning the protection of*
 7 *confidential commercial information and trade se-*
 8 *crets.”.*

9 **“SEC. 39900–1. USE OF CIVIL PENALTY AMOUNTS.**

10 *“The Secretary shall, without further appropriation,*
 11 *collect civil penalties under section 39900 and use the*
 12 *funds derived from such civil penalties, in addition to any*
 13 *other amounts available to the Secretary, to carry out ac-*
 14 *tivities described in this part and to improve consumer and*
 15 *provider information about drug value and drug price*
 16 *transparency.*

17 **“SEC. 39900–2. ANNUAL REPORT TO CONGRESS.**

18 *“(a) IN GENERAL.—Subject to subsection (b), the Sec-*
 19 *retary shall submit to Congress, and post on the public*
 20 *website of the Department of Health and Human Services*
 21 *in a way that is easy to find, use, and understand, an an-*
 22 *nual report—*

23 *“(1) summarizing the information reported pur-*
 24 *suant to section 39900; and*

1 “(2) including copies of the reports and sup-
 2 porting detailed economic analyses submitted pursu-
 3 ant to such section.

4 “(b) *TRADE SECRETS AND CONFIDENTIAL INFORMA-*
 5 *TION.—In carrying out this section the Secretary shall en-*
 6 *force current law concerning the protection of confidential*
 7 *commercial information and trade secrets.”.*

8 ***TITLE III—IMPROVING TRANSPARENCY IN HEALTH CARE***
 9

10 ***SEC. 301. INCREASING TRANSPARENCY BY REMOVING GAG***
 11 ***CLAUSES ON PRICE AND QUALITY INFORMA-***
 12 ***TION.***

13 *Subpart II of part A of title XXVII of the Public*
 14 *Health Service Act (42 U.S.C. 300gg–11 et seq.), as amend-*
 15 *ed by section 103, is amended by adding at the end the*
 16 *following:*

17 ***“SEC. 2729B. INCREASING TRANSPARENCY BY REMOVING***
 18 ***GAG CLAUSES ON PRICE AND QUALITY IN-***
 19 ***FORMATION.***

20 ***“(a) INCREASING PRICE AND QUALITY TRANSPARENCY***
 21 ***FOR PLAN SPONSORS AND GROUP AND INDIVIDUAL MAR-***
 22 ***KET AND CONSUMERS.—***

23 ***“(1) GROUP HEALTH PLANS.—A group health***
 24 *plan or health insurance issuer offering group health*
 25 *insurance coverage may not enter into an agreement*

1 *with a health care provider, network or association of*
2 *providers, third-party administrator, or other service*
3 *provider offering access to a network of providers that*
4 *would directly or indirectly restrict a group health*
5 *plan or health insurance issuer from—*

6 “(A) *providing provider-specific cost or*
7 *quality of care information, through a consumer*
8 *engagement tool or any other means, to referring*
9 *providers, the plan sponsor, enrollees, or eligible*
10 *enrollees of the plan or coverage;*

11 “(B) *electronically accessing de-identified*
12 *claims and encounter data for each enrollee in*
13 *the plan or coverage, upon request and consistent*
14 *with the privacy regulations promulgated pursu-*
15 *ant to section 264(c) of the Health Insurance*
16 *Portability and Accountability Act, the amend-*
17 *ments to this Act made by the Genetic Informa-*
18 *tion Nondiscrimination Act of 2008, and the*
19 *Americans with Disabilities Act of 1990, with*
20 *respect to the applicable health plan or health*
21 *insurance coverage, including, on a per claim*
22 *basis—*

23 “(i) *financial information, such as the*
24 *allowed amount, or any other claim-related*

1 *financial obligations included in the pro-*
 2 *vider contract;*

3 “(ii) *provider information, including*
 4 *name and clinical designation;*

5 “(iii) *service codes; or*

6 “(iv) *any other data element normally*
 7 *included in claim or encounter transactions*
 8 *when received by a plan or issuer; or*

9 “(C) *sharing data described in subpara-*
 10 *graph (A) or (B) with a business associate as de-*
 11 *finied in section 160.103 of title 45, Code of Fed-*
 12 *eral Regulations (or successor regulations), con-*
 13 *sistent with the privacy regulations promulgated*
 14 *pursuant to section 264(c) of the Health Insur-*
 15 *ance Portability and Accountability Act, the*
 16 *amendments to this Act made by the Genetic In-*
 17 *formation Nondiscrimination Act of 2008, and*
 18 *the Americans with Disabilities Act of 1990.*

19 “(2) *INDIVIDUAL HEALTH INSURANCE COV-*
 20 *ERAGE.—A health insurance issuer offering indi-*
 21 *vidual health insurance coverage may not enter into*
 22 *an agreement with a health care provider, network or*
 23 *association of providers, or other service provider of-*
 24 *fering access to a network of providers that would di-*

1 *rectly or indirectly restrict the health insurance issuer*
 2 *from—*

3 *“(A) providing provider-specific price or*
 4 *quality of care information, through a consumer*
 5 *engagement tool or any other means, to referring*
 6 *providers, enrollees, or eligible enrollees of the*
 7 *plan or coverage; or*

8 *“(B) sharing, for plan design, plan admin-*
 9 *istration, and plan, financial, legal, and quality*
 10 *improvement activities, data described in sub-*
 11 *paragraph (A) with a business associate as de-*
 12 *finied in section 160.103 of title 45, Code of Fed-*
 13 *eral Regulations (or successor regulations), con-*
 14 *sistent with the privacy regulations promulgated*
 15 *pursuant to section 264(c) of the Health Insur-*
 16 *ance Portability and Accountability Act, the*
 17 *amendments to this Act made by the Genetic In-*
 18 *formation Nondiscrimination Act of 2008, and*
 19 *the Americans with Disabilities Act of 1990.*

20 *“(3) CLARIFICATION REGARDING PUBLIC DISCLO-*
 21 *SURE OF INFORMATION.—Nothing in paragraph*
 22 *(1)(A) or (2)(A) prevents a health care provider, net-*
 23 *work or association of providers, or other service pro-*
 24 *vider from placing reasonable restrictions on the pub-*

1 *lic disclosure of the information described in such*
 2 *paragraphs (1) and (2).*

3 “(4) *ATTESTATION.*—A group health plan or a
 4 *health insurance issuer offering group or individual*
 5 *health insurance coverage shall annually submit to,*
 6 *as applicable, the applicable authority described in*
 7 *section 2723 or the Secretary of Labor, an attestation*
 8 *that such plan or issuer is in compliance with the re-*
 9 *quirements of this subsection.*

10 “(5) *RULE OF CONSTRUCTION.*—Nothing in this
 11 *section shall be construed to otherwise limit group*
 12 *health plan, plan sponsor, or health insurance issuer*
 13 *access to data currently permitted under the privacy*
 14 *regulations promulgated pursuant to section 264(c) of*
 15 *the Health Insurance Portability and Accountability*
 16 *Act, the amendments to this Act made by the Genetic*
 17 *Information Nondiscrimination Act of 2008, and the*
 18 *Americans with Disabilities Act of 1990.”.*

19 **SEC. 302. BANNING ANTICOMPETITIVE TERMS IN FACILITY**
 20 **AND INSURANCE CONTRACTS THAT LIMIT AC-**
 21 **CESS TO HIGHER QUALITY, LOWER COST**
 22 **CARE.**

23 (a) *IN GENERAL.*—Section 2729B of the Public Health
 24 *Service Act, as added by section 301, is amended by adding*
 25 *at the end the following:*

1 “(b) *PROTECTING HEALTH PLANS NETWORK DESIGN*
2 *FLEXIBILITY.*—

3 “(1) *IN GENERAL.*—*A group health plan or a*
4 *health insurance issuer offering group or individual*
5 *health insurance coverage shall not enter into an*
6 *agreement with a provider, network or association of*
7 *providers, or other service provider offering access to*
8 *a network of service providers if such agreement, di-*
9 *rectly or indirectly—*

10 “(A) *restricts the group health plan or*
11 *health insurance issuer from—*

12 “(i) *directing or steering enrollees to*
13 *other health care providers; or*

14 “(ii) *offering incentives to encourage*
15 *enrollees to utilize specific health care pro-*
16 *viders; or*

17 “(B) *requires the group health plan or*
18 *health insurance issuer to enter into any addi-*
19 *tional contract with an affiliate of the provider,*
20 *such as an affiliate of the provider, as a condi-*
21 *tion of entering into a contract with such pro-*
22 *vider;*

23 “(C) *requires the group health plan or*
24 *health insurance issuer to agree to payment rates*

1 *or other terms for any affiliate not party to the*
 2 *contract of the provider involved; or*

3 “(D) *restricts other group health plans or*
 4 *health insurance issuers not party to the contract*
 5 *from paying a lower rate for items or services*
 6 *than the contracting plan or issuer pays for such*
 7 *items or services.*

8 “(2) *ADDITIONAL REQUIREMENT FOR SELF-IN-*
 9 *SURED PLANS.—A self-insured group health plan*
 10 *shall not enter into an agreement with a provider,*
 11 *network or association of providers, third-party ad-*
 12 *ministrator, or other service provider offering access*
 13 *to a network of providers if such agreement directly*
 14 *or indirectly requires the group health plan to certify,*
 15 *attest, or otherwise confirm in writing that the group*
 16 *health plan is bound by restrictive contracting terms*
 17 *between the service provider and a third-party ad-*
 18 *ministrator that the group health plan is not party*
 19 *to, without a disclosure that such terms exist.*

20 “(3) *EXCEPTION FOR CERTAIN GROUP MODEL*
 21 *ISSUERS.—Paragraph (1)(A) shall not apply to a*
 22 *group health plan or health insurance issuer offering*
 23 *group or individual health insurance coverage with*
 24 *respect to—*

1 “(A) a health maintenance organization (as
 2 defined in section 2791(b)(3)), if such health
 3 maintenance organization operates primarily
 4 through exclusive contracts with multi-specialty
 5 physician groups, nor to any arrangement be-
 6 tween such a health maintenance organization
 7 and its affiliates; or

8 “(B) a value-based network arrangement,
 9 such as an exclusive provider network, account-
 10 able care organization, center of excellence, a
 11 provider sponsored health insurance issuer that
 12 operates primarily through aligned multi-spe-
 13 cialty physician group practices or integrated
 14 health systems, or such other similar network ar-
 15 rangements as determined by the Secretary
 16 through rulemaking.

17 “(4) ATTESTATION.—A group health plan or
 18 health insurance issuer offering group or individual
 19 health insurance coverage shall annually submit to,
 20 as applicable, the applicable authority described in
 21 section 2723 or the Secretary of Labor, an attestation
 22 that such plan or issuer is in compliance with the re-
 23 quirements of this subsection.

24 “(c) MAINTENANCE OF EXISTING HIPAA, GINA, AND
 25 ADA PROTECTIONS.—Nothing in this section shall modify,

1 *reduce, or eliminate the existing privacy protections and*
 2 *standards provided by reason of State and Federal law, in-*
 3 *cluding the requirements of parts 160 and 164 of title 45,*
 4 *Code of Federal Regulations (or any successor regulations).*

5 “(d) *REGULATIONS.—The Secretary, not later than 1*
 6 *year after the date of enactment of the Lower Health Care*
 7 *Costs Act, shall promulgate regulations to carry out this*
 8 *section.*

9 “(e) *RULE OF CONSTRUCTION.—Nothing in this sec-*
 10 *tion shall be construed to limit network design or cost or*
 11 *quality initiatives by a group health plan or health insur-*
 12 *ance issuer, including accountable care organizations, ex-*
 13 *clusive provider organizations, networks that tier providers*
 14 *by cost or quality or steer enrollees to centers of excellence,*
 15 *or other pay-for-performance programs.*

16 “(f) *CLARIFICATION WITH RESPECT TO ANTITRUST*
 17 *LAWS.—Compliance with this section does not constitute*
 18 *compliance with the antitrust laws, as defined in subsection*
 19 *(a) of the first section of the Clayton Act (15 U.S.C.*
 20 *12(a)).”.*

21 “(b) *EFFECTIVE DATE.—Section 2729B of the Public*
 22 *Health Service Act (as added by section 301 and amended*
 23 *by subsection (a)) shall apply with respect to any contract*
 24 *entered into on or after the date that is 18 months after*
 25 *the date of enactment of this Act. With respect to an appli-*

1 *cable contract that is in effect on the date of enactment of*
 2 *this Act, such section 2729B shall apply on the earlier of*
 3 *the date of renewal of such contract or 3 years after such*
 4 *date of enactment.*

5 **SEC. 303. DESIGNATION OF A NONGOVERNMENTAL, NON-**
 6 **PROFIT TRANSPARENCY ORGANIZATION TO**
 7 **LOWER AMERICANS' HEALTH CARE COSTS.**

8 *(a) IN GENERAL.—Subpart C of title XXVII of the*
 9 *Public Health Service Act (42 U.S.C. 300gg–91 et seq.), as*
 10 *amended by section 102, is further amended by adding at*
 11 *the end the following:*

12 **“SEC. 2796. DESIGNATION OF A NONGOVERNMENTAL, NON-**
 13 **PROFIT TRANSPARENCY ORGANIZATION TO**
 14 **LOWER AMERICANS' HEALTH CARE COSTS.**

15 *“(a) IN GENERAL.—The Secretary, in consultation*
 16 *with the Secretary of Labor, not later than 1 year after*
 17 *the date of enactment of the Lower Health Care Costs Act,*
 18 *shall enter into a contract with a nonprofit entity to sup-*
 19 *port the establishment and maintenance of a database that*
 20 *receives and utilizes health care claims information and re-*
 21 *lated information and issues reports that are available to*
 22 *the public and authorized users, and are submitted to the*
 23 *Department of Health and Human Services.*

24 *“(b) REQUIREMENTS.—*

1 “(1) *IN GENERAL.*—*The database established*
2 *under subsection (a) shall—*

3 “(A) *improve transparency by using de-*
4 *identified health care data to—*

5 “(i) *inform patients about the cost,*
6 *quality, and value of their care;*

7 “(ii) *assist providers and hospitals, as*
8 *they work with patients, to make informed*
9 *choices about care;*

10 “(iii) *enable providers, hospitals, and*
11 *communities to improve services and out-*
12 *comes for patients by benchmarking their*
13 *performance against that of other providers,*
14 *hospitals, and communities;*

15 “(iv) *enable purchasers, including em-*
16 *ployers, employee organizations, and health*
17 *plans, to develop value-based purchasing*
18 *models, improve quality, and reduce the cost*
19 *of health care and insurance coverage for*
20 *enrollees;*

21 “(v) *enable employers and employee or-*
22 *ganizations to evaluate network design and*
23 *construction, and the cost of care for enroll-*
24 *ees;*

1 “(vi) *facilitate State-led initiatives to*
2 *lower health care costs and improve quality;*
3 *and*

4 “(vii) *promote competition based on*
5 *quality and cost;*

6 “(B) *collect medical claims, prescription*
7 *drug claims, and remittance data consistent with*
8 *the protections and requirements of subsection*
9 *(d);*

10 “(C) *be established in such a manner that*
11 *allows the data collected pursuant to subpara-*
12 *graph (B) to be shared with any State all-payer*
13 *claims database or regional database operated*
14 *with authorization from States, at cost, using a*
15 *standardized format, if such State or regional*
16 *database also submits claims data to the data-*
17 *base established under this section; and*

18 “(D) *be available to—*

19 “(i) *the Director of the Congressional*
20 *Budget Office, the Comptroller General of*
21 *the United States, the Executive Director of*
22 *the Medicare Payment Advisory Commis-*
23 *sion, and the Executive Director of the Med-*
24 *icaid and CHIP Payment Advisory Com-*
25 *mission, upon request, subject to the privacy*

1 *and security requirements of authorized*
 2 *users under subsection (e)(2); and*

3 “(ii) *authorized users, including em-*
 4 *ployers, employee organizations, providers,*
 5 *researchers, and policymakers, subject to*
 6 *subsection (e).*

7 “(2) *PRIVACY AND SECURITY; BREACH NOTIFICA-*
 8 *TIONS.—*

9 “(A) *REGULATIONS.—*

10 “(i) *IN GENERAL.—The Secretary shall*
 11 *issue regulations prescribing the extent to*
 12 *which, and the manner in which, the fol-*
 13 *lowing rules (and any successors of such*
 14 *rules) shall apply to the activities under*
 15 *this section of an entity receiving a contract*
 16 *under subsection (a):*

17 “(I) *The Privacy Rule under part*
 18 *160 and subparts A and E of part 164*
 19 *of title 45, Code of Federal Regulations*
 20 *(or any successor regulations).*

21 “(II) *The Security Rule under*
 22 *part 160 and subparts A and C of part*
 23 *164 of such title 45 (or any successor*
 24 *regulations).*

1 “(III) *The Breach Notification*
 2 *Rule under part 160 and subparts A*
 3 *and D of part 164 of such title 45 (or*
 4 *any successor regulations).*

5 “(ii) *SUPPLEMENTAL REGULATIONS.—*
 6 *In order to ensure data privacy and secu-*
 7 *rity and the notification of breaches, the*
 8 *Secretary may issue such supplemental reg-*
 9 *ulations on the subjects of the rules listed*
 10 *under clause (i) as the Secretary determines*
 11 *appropriate to address differences between*
 12 *the activities described by this section and*
 13 *the activities covered by such rules.*

14 “(B) *ENFORCEMENT.—Section 1176 of So-*
 15 *cial Security Act shall apply with respect to a*
 16 *violation of this paragraph in the same manner*
 17 *such section 1176 applies to a violation of part*
 18 *C of title XI of the Social Security Act, and the*
 19 *Secretary may include in the regulations pro-*
 20 *mulgated under this section provisions to apply*
 21 *such section to this paragraph.*

22 “(C) *PROCEDURE.—*

23 “(i) *TIMING.—The Secretary shall*
 24 *issue the initial set of regulations under this*
 25 *paragraph not later than 1 year after the*

1 *date of enactment of the Lower Health Care*
2 *Costs Act.*

3 “(ii) *AUTHORITY TO USE INTERIM*
4 *FINAL PROCEDURES.—The Secretary may*
5 *make such initial set of regulations effective*
6 *and final immediately upon issuance, on an*
7 *interim basis, and provide for a period of*
8 *public comment on such initial set of regu-*
9 *lations after the date of publication.*

10 “(D) *REQUIREMENTS OF ENTITY.—The en-*
11 *tity receiving the contract under this section*
12 *shall—*

13 “(i) *not disclose to the public any indi-*
14 *vidually identifiable health information or*
15 *proprietary financial information;*

16 “(ii) *strictly limit staff access to the*
17 *data to staff with appropriate training,*
18 *clearance, and background checks and re-*
19 *quire regular privacy and security training;*

20 “(iii) *maintain effective security*
21 *standards for transferring data or making*
22 *data available to authorized users;*

23 “(iv) *develop a process for providing*
24 *access to data to authorized users, in a se-*

1 *cure manner that maintains privacy and*
 2 *confidentiality of data; and*

3 “(v) *adhere to current best security*
 4 *practices with respect to the management*
 5 *and use of such data for health services re-*
 6 *search, in accordance with applicable Fed-*
 7 *eral privacy law*

8 “(3) *CONSULTATION.—*

9 “(A) *ADVISORY COMMITTEE.—Not later*
 10 *than 180 days after the date of enactment of the*
 11 *Lower Health Care Costs Act, the Secretary shall*
 12 *convene an Advisory Committee (referred to in*
 13 *this section as the ‘Committee’), consisting of 13*
 14 *members, to advise the Secretary, the contracting*
 15 *entity, and Congress on the establishment, oper-*
 16 *ations, and use of the database established under*
 17 *this section.*

18 “(B) *MEMBERSHIP.—*

19 “(i) *APPOINTMENT.—In accordance*
 20 *with clause (ii), the Secretary, in consulta-*
 21 *tion with the Secretary of Labor and the*
 22 *Comptroller General of the United States*
 23 *shall, not later than 180 days after the date*
 24 *of enactment of the Lower Health Care*
 25 *Costs Act, appoint members to the Com-*

1 *mittee who have distinguished themselves in*
 2 *the fields of health services research, health*
 3 *economics, health informatics, or the gov-*
 4 *ernance of State all-payer claims databases,*
 5 *or who represent organizations likely to sub-*
 6 *mit data to or use the database, including*
 7 *patients, employers, or employee organiza-*
 8 *tions that sponsor group health plans,*
 9 *health care providers, health insurance*
 10 *issuers, or third-party administrators of*
 11 *group health plans. Such members shall*
 12 *serve 3-year terms on a staggered basis. Va-*
 13 *cancies on the Committee shall be filled by*
 14 *appointment consistent with this subsection*
 15 *not later than 3 months after the vacancy*
 16 *arises.*

17 *“(ii) COMPOSITION.—In accordance*
 18 *with clause (i)—*

19 *“(I) the Secretary, in consultation*
 20 *with the Secretary of Labor, shall ap-*
 21 *point to the Committee—*

22 *“(aa) 1 member selected by*
 23 *the Secretary, in coordination*
 24 *with the Secretary of Labor, to*

1 *serve as the chair of the Com-*
2 *mittee;*

3 *“(bb) the Assistant Secretary*
4 *for Planning and Evaluation of*
5 *the Department of Health and*
6 *Human Services, or a designee of*
7 *such Assistant Secretary;*

8 *“(cc) 1 representative of the*
9 *Centers for Medicare & Medicaid*
10 *Services;*

11 *“(dd) 1 representative of the*
12 *Agency for Health Research and*
13 *Quality;*

14 *“(ee) 1 representative of the*
15 *Office for Civil Rights of the De-*
16 *partment of Health and Human*
17 *Services with expertise in data*
18 *privacy and security;*

19 *“(ff) 1 representative of the*
20 *National Center for Health Statis-*
21 *tics; and*

22 *“(gg) 1 representative of the*
23 *Employee Benefits and Security*
24 *Administration of the Department*
25 *of Labor; and*

1 “(II) the Comptroller General of
2 the United States shall appoint to the
3 Committee—

4 “(aa) 1 representative of an
5 employer that sponsors a group
6 health plan;

7 “(bb) 1 representative of an
8 employee organization that spon-
9 sors a group health plan;

10 “(cc) 1 academic researcher
11 with expertise in health economics
12 or health services research;

13 “(dd) 1 consumer advocate;
14 and

15 “(ee) 2 additional members.

16 “(C) DUTIES.—The Committee shall—

17 “(i) advise the Secretary on the man-
18 agement of the contract under subsection
19 (a);

20 “(ii) assist and advise the entity re-
21 ceiving the contract under subsection (a) in
22 establishing—

23 “(I) the scope and format of the
24 data to be submitted under subsection
25 (d);

1 “(II) best practices with respect to
2 de-identification of data, as appro-
3 priate;

4 “(III) the appropriate uses of
5 data by authorized users, including de-
6 veloping standards for the approval of
7 requests by organizations to access and
8 use the data; and

9 “(IV) the appropriate formats and
10 methods for making reports and anal-
11 yses based on the database to the pub-
12 lic;

13 “(iii) conduct an annual review of
14 whether data was used according to the ap-
15 propriate uses as described in clause
16 (ii)(II), and advise the designated entity on
17 using the data for authorized purposes;

18 “(iv) report, as appropriate, to the
19 Secretary and Congress on the operation of
20 the database and opportunities to better
21 achieve the objectives of this section;

22 “(v) establish additional restrictions on
23 researchers who receive compensation from
24 entities described in subsection (e)(2)(B)(ii),

1 *in order to protect proprietary financial in-*
 2 *formation; and*

3 “(vi) *establish objectives for research*
 4 *and public reporting.*

5 “(4) *STATE REQUIREMENTS.—A State may re-*
 6 *quire health insurance issuers and other payers to*
 7 *submit claims data to the database established under*
 8 *this section, provided that such data is submitted to*
 9 *the entity awarded the contract under this section in*
 10 *a form and manner established by the Secretary, and*
 11 *pursuant to subsection (d)(4)(B).*

12 “(5) *SANCTIONS.—The Secretary shall take ap-*
 13 *propriate action to sanction users who attempt to re-*
 14 *identify data accessed pursuant to paragraph (1)(D).*

15 “(c) *CONTRACT REQUIREMENTS.—*

16 “(1) *COMPETITIVE PROCEDURES.—The Secretary*
 17 *shall enter into the contract under subsection (a)*
 18 *using full and open competition procedures pursuant*
 19 *to chapter 33 of title 41, United States Code.*

20 “(2) *ELIGIBLE ENTITIES.—To be eligible to enter*
 21 *into a contract described in subsection (a), an entity*
 22 *shall—*

23 “(A) *be a private nonprofit entity governed*
 24 *by a board that includes representatives of the*
 25 *academic research community and individuals*

1 *with expertise in employer-sponsored insurance,*
 2 *research using health care claims data and actu-*
 3 *arial analysis;*

4 “(B) *conduct its business in an open and*
 5 *transparent manner that provides the oppor-*
 6 *tunity for public comment on its activities; and*

7 “(C) *agree to comply with any requirements*
 8 *imposed under the rulemaking described in sub-*
 9 *section (d)(4)(A).*

10 “(3) *CONSIDERATIONS.—In awarding the con-*
 11 *tract under subsection (a), the Secretary shall con-*
 12 *sider an entity’s experience in—*

13 “(A) *health care claims data collection, ag-*
 14 *gregation, quality assurance, analysis, and secu-*
 15 *rity;*

16 “(B) *supporting academic research on*
 17 *health costs, spending, and utilization for and by*
 18 *privately insured patients;*

19 “(C) *working with large health insurance*
 20 *issuers and third-party administrators to assem-*
 21 *ble a national claims database;*

22 “(D) *effectively collaborating with and en-*
 23 *gaging stakeholders to develop reports;*

24 “(E) *meeting budgets and timelines, includ-*
 25 *ing in connection with report generation; and*

1 “(F) *facilitating the creation of, or sup-*
 2 *porting, State all-payer claims databases.*

3 “(4) *CONTRACT TERM.—A contract awarded*
 4 *under this section shall be for a period of 5 years, and*
 5 *may be renewed after a subsequent competitive bid-*
 6 *ding process under this section.*

7 “(5) *TRANSITION OF CONTRACT.—If the Sec-*
 8 *retary, following a competitive process at the end of*
 9 *the contract period, selects a new entity to maintain*
 10 *the database, all data shall be transferred to the new*
 11 *entity according to a schedule and process to be deter-*
 12 *mined by the Secretary. Upon termination of a con-*
 13 *tract, no entity may keep data held by the database*
 14 *or disclose such data to any entity other than the en-*
 15 *tity so designated by the Secretary. The Secretary*
 16 *shall include enforcement terms in any contract with*
 17 *an organization chosen under this section, to ensure*
 18 *the timely transfer of all data, and any associated*
 19 *code or algorithms, to a new entity in the event of*
 20 *contract termination.*

21 “(d) *RECEIVING HEALTH INFORMATION.—*

22 “(1) *REQUIREMENTS.—*

23 “(A) *IN GENERAL.—The Secretary of Labor*
 24 *shall ensure that the applicable self-insured*
 25 *group health plan, through its third-party ad-*

1 *ministrator, pharmacy benefit manager, or other*
 2 *entity designated by the group health plan, as*
 3 *applicable, electronically submits all claims data*
 4 *with respect to the plan, pursuant to subpara-*
 5 *graph (B).*

6 *“(B) SCOPE OF INFORMATION AND FORMAT*
 7 *OF SUBMISSION.—The entity awarded the con-*
 8 *tract under subsection (a), in consultation with*
 9 *the Committee described in subsection (b)(3), and*
 10 *pursuant to the privacy and security require-*
 11 *ments of subsection (b)(2), shall—*

12 *“(i) specify the data elements required*
 13 *to be submitted under subparagraph (A),*
 14 *which shall include all data related to*
 15 *transactions described in subparagraphs (A)*
 16 *and (E) of section 1173(a)(2) of the Social*
 17 *Security Act, including all data elements*
 18 *normally present in such transactions when*
 19 *adjudicated, and enrollment information;*

20 *“(ii) specify the form and manner for*
 21 *such submissions, and the historical period*
 22 *to be included in the initial submission;*
 23 *and*

1 “(iii) offer an automated submission
2 option to minimize administrative burdens
3 for entities required to submit data.

4 “(C) *DE-IDENTIFICATION OF DATA.*—The
5 entity awarded the contract under subsection (a)
6 shall—

7 “(i) establish a process under which
8 data is de-identified consistent with the de-
9 identification requirements under section
10 164.514 of title 45, Code of Federal Regula-
11 tions (or any successor regulations), while
12 retaining the ability to link data longitu-
13 dinally for the purposes of research on cost
14 and quality, and the ability to complete
15 risk adjustment and geographic analysis;

16 “(ii) ensure that any third-party sub-
17 contractors who perform the de-identifica-
18 tion process described in clause (i) retain
19 only the minimum necessary information to
20 perform such a process, and adhere to effec-
21 tive security and encryption practices in
22 data storage and transmission;

23 “(iii) store claims and other data col-
24 lected under this subsection only in de-iden-
25 tified form, in accordance with section

1 164.514 of title 45, Code of Federal Regula-
2 tions (or any successor regulations); and

3 “(iv) ensure that individually identifi-
4 able data is encrypted, in accordance with
5 guidance issued by the Secretary under sec-
6 tion 13402(h)(2) of the HITECH Act.

7 “(2) *APPLICABLE SELF-INSURED GROUP HEALTH*
8 *PLAN.*—For purposes of paragraph (1), a self-insured
9 group health plan is an applicable self-insured group
10 health plan if such plan is self-administered, or is ad-
11 ministered by a third-party plan administrator that
12 meets 1 or both of the following criteria:

13 “(A) Administers health, medical, or phar-
14 macy benefits for more than 50,000 enrollees.

15 “(B) Is one of the 5 largest administrators
16 or issuers of self-insured group health plans in a
17 State in which such administrator operates, as
18 measured by the aggregate number of enrollees in
19 plans administered by such administrator in
20 such State, as determined by the Secretary.

21 “(3) *THIRD-PARTY ADMINISTRATORS.*—In the
22 case of a third-party administrator that is required
23 under this subsection to submit claims data with re-
24 spect to an applicable self-insured group health plan,
25 such administrator shall submit claims data with re-

1 *spect to all self-insured group health plans that the*
 2 *administrator administers, including such plans that*
 3 *are not applicable self-insured group health plans, as*
 4 *described in paragraph (2).*

5 “(4) *RECEIVING OTHER INFORMATION.*—

6 “(A) *MEDICARE DATA.*—*The Secretary,*
 7 *through rulemaking, shall ensure that the data*
 8 *made available to such entity is available to*
 9 *qualified entities under section 1874(e) of the So-*
 10 *cial Security Act is made available to the entity*
 11 *awarded a contract under subsection (a).*

12 “(B) *STATE DATA.*—*The entity awarded the*
 13 *contract under subsection (a) shall collect data*
 14 *from State all payer claims databases that seek*
 15 *access to the database established under this sec-*
 16 *tion.*

17 “(5) *AVAILABILITY OF DATA.*—*An entity re-*
 18 *quired to submit data under this subsection may not*
 19 *place any restrictions on the use of such data by au-*
 20 *thorized users.*

21 “(e) *USES OF INFORMATION.*—

22 “(1) *IN GENERAL.*—*The entity awarded the con-*
 23 *tract under subsection (a) shall make the database*
 24 *available to users who are authorized under this sub-*

1 *section, at cost, and reports and analyses based on the*
 2 *data available to the public with no charge.*

3 *“(2) AUTHORIZATION OF USERS.—*

4 *“(A) IN GENERAL.—An entity may request*
 5 *authorization by the entity awarded the contract*
 6 *under subsection (a) for access to the database in*
 7 *accordance with this paragraph.*

8 *“(B) APPLICATION.—An entity desiring au-*
 9 *thorization under this paragraph shall submit to*
 10 *the entity awarded the contract an application*
 11 *for such access, which shall include—*

12 *“(i) in the case of an entity requesting*
 13 *access for research purposes—*

14 *“(I) a description of the uses and*
 15 *methodologies for evaluating health*
 16 *system performance using such data;*
 17 *and*

18 *“(II) documentation of approval*
 19 *of the research by an institutional re-*
 20 *view board, if applicable for a par-*
 21 *ticular plan of research; or*

22 *“(ii) in the case of an entity such as*
 23 *an employer, health insurance issuer, third-*
 24 *party administrator, or health care pro-*
 25 *vider, requesting access for the purpose of*

1 *quality improvement or cost-containment, a*
2 *description of the intended uses for such*
3 *data.*

4 “(C) *REQUIREMENTS.*—

5 “(i) *RESEARCH.*—Upon approval of an
6 *application for research purposes under*
7 *subparagraph (B)(i), the authorized user*
8 *shall enter into a data use and confiden-*
9 *tiality agreement with the entity awarded*
10 *the contract under subsection (a), which*
11 *shall include a prohibition on attempts to*
12 *reidentify and disclose individually identifi-*
13 *able health information and proprietary fi-*
14 *nancial information.*

15 “(ii) *QUALITY IMPROVEMENT AND*
16 *COST-CONTAINMENT.*—In consultation with
17 *the Committee described in subsection*
18 *(b)(3), the Secretary shall, through rule-*
19 *making, establish the form and manner in*
20 *which authorized users described in sub-*
21 *paragraph (B)(ii) may access data. Data*
22 *provided to such authorized users shall be*
23 *provided in a form and manner such that*
24 *users may not obtain individually identifi-*
25 *able price information with respect to direct*

1 competitors. Upon approval, such author-
 2 ized user shall enter into a data use and
 3 confidentiality agreement with the entity.

4 “(iii) *CUSTOMIZED REPORTS.*—Em-
 5 ployers and employer organizations may re-
 6 quest customized reports from the entity
 7 awarded the contract under subsection (a),
 8 at cost, subject to the requirements of this
 9 section with respect to privacy, security,
 10 and proprietary financial information.

11 “(iv) *NON-CUSTOMIZED REPORTS.*—
 12 The entity awarded the contract under sub-
 13 section (a), in consultation with the Com-
 14 mittee, shall make available to all author-
 15 ized users aggregate data sets, free of charge.

16 “(f) *FUNDING.*—

17 “(1) *INITIAL FUNDING.*—There are authorized to
 18 be appropriated, and there are appropriated, out of
 19 monies in the Treasury not otherwise appropriated,
 20 \$20,000,000 for fiscal year 2020, for the implementa-
 21 tion of the initial contract and establishment of the
 22 database under this section.

23 “(2) *ONGOING FUNDING.*—There are authorized
 24 to be appropriated \$15,000,000 for each of fiscal
 25 years 2021 through 2025, for purposes of carrying out

1 *this section (other than the grant program under sub-*
 2 *section (h)).*

3 *“(g) ANNUAL REPORT.—*

4 *“(1) SUBMISSION.—On each of the dates de-*
 5 *scribed in paragraph (2), the entity receiving the con-*
 6 *tract under subsection (a) shall submit to Congress,*
 7 *the Secretary of Health and Human Services, and the*
 8 *Secretary of Labor and publish online for access by*
 9 *the general public, a report containing a description*
 10 *of—*

11 *“(A) trends in the price, utilization, and*
 12 *total spending on health care services, including*
 13 *a geographic analysis of differences in such*
 14 *trends;*

15 *“(B) limitations in the data set;*

16 *“(C) progress towards the objectives of this*
 17 *section; and*

18 *“(D) the performance by the entity of the*
 19 *duties required under such contract.*

20 *“(2) DATES DESCRIBED.—The reports described*
 21 *in paragraph (1) shall be submitted—*

22 *“(A) not later than 3 years after the date*
 23 *of enactment of the Lower Health Care Costs Act;*

24 *“(B) the later of 1 year after the date that*
 25 *is 3 years after such date of enactment or March*

1 *1 of the year after the date that is 3 years after*
 2 *such date of enactment; and*

3 “(C) *March 1 of each year thereafter.*

4 “(3) *PUBLIC REPORTS AND RESEARCH.—The en-*
 5 *tity receiving a contract under subsection (a) shall, in*
 6 *coordination with authorized users, make analyses*
 7 *and research available to the public on an ongoing*
 8 *basis to promote the objectives of this section.*

9 “(h) *GRANTS TO STATES.—*

10 “(1) *IN GENERAL.—The Secretary, in consulta-*
 11 *tion with the Secretary of Labor, may award grants*
 12 *to States for the purpose of establishing and main-*
 13 *taining State all-payer claims databases that improve*
 14 *transparency of data in order to meet the goals of*
 15 *subsection (a)(1).*

16 “(2) *REQUIREMENT.—To be eligible to receive*
 17 *the funding under paragraph (1), a State shall sub-*
 18 *mit data to the database as described in subsection*
 19 *(b)(1)(C), using the format described in subsection*
 20 *(d)(1).*

21 “(3) *FUNDING.—There is authorized to be appro-*
 22 *priated \$100,000,000 for the period of fiscal years*
 23 *2020 through 2029 for the purpose of awarding*
 24 *grants to States under this subsection.*

25 “(i) *EXEMPTION FROM PUBLIC DISCLOSURE.—*

1 “(1) *IN GENERAL.*—*Claims data provided to the*
 2 *database, and the database itself shall not be consid-*
 3 *ered public records and shall be exempt from public*
 4 *disclosure requirements.*

5 “(2) *RESTRICTIONS ON USES FOR CERTAIN PRO-*
 6 *CEEDINGS.*—*Data disclosed to authorized users shall*
 7 *not be subject to discovery or admission as public in-*
 8 *formation, or evidence in judicial or administrative*
 9 *proceedings without consent of the affected parties.*

10 “(j) *DEFINITIONS.*—

11 “(1) *INDIVIDUALLY IDENTIFIABLE HEALTH IN-*
 12 *FORMATION.*—*The term ‘individually identifiable*
 13 *health information’ has the meaning given such term*
 14 *in section 1171(6) of the Social Security Act.*

15 “(2) *PROPRIETARY FINANCIAL INFORMATION.*—
 16 *The term ‘proprietary financial information’ means*
 17 *data that would disclose the terms of a specific con-*
 18 *tract between an individual health care provider or*
 19 *facility and a specific group health plan, Medicaid*
 20 *managed care organization or other managed care en-*
 21 *tity, or health insurance issuer offering group or indi-*
 22 *vidual coverage.*

23 “(k) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*
 24 *tion shall be construed to affect or modify enforcement of*
 25 *the privacy, security, or breach notification rules promul-*

1 *gated under section 264(c) of the Health Insurance Port-*
 2 *ability and Accountability Act of 1996 (or successor regula-*
 3 *tions).”.*

4 *(b) GAO REPORT.—*

5 *(1) IN GENERAL.—The Comptroller General of*
 6 *the United States shall conduct a study on—*

7 *(A) the performance of the entity awarded*
 8 *a contract under section 2795(a) of the Public*
 9 *Health Service Act, as added by subsection (a),*
 10 *under such contract;*

11 *(B) the privacy and security of the informa-*
 12 *tion reported to the entity; and*

13 *(C) the costs incurred by such entity in per-*
 14 *forming such duties.*

15 *(2) REPORTS.—Not later than 2 years after the*
 16 *effective date of the first contract entered into under*
 17 *section 2795(a) of the Public Health Service Act, as*
 18 *added by subsection (a), and again not later than 4*
 19 *years after such effective date, the Comptroller Gen-*
 20 *eral of the United States shall submit to Congress a*
 21 *report containing the results of the study conducted*
 22 *under paragraph (1), together with recommendations*
 23 *for such legislation and administrative action as the*
 24 *Comptroller General determines appropriate.*

1 **SEC. 304. PROTECTING PATIENTS AND IMPROVING THE AC-**
 2 **CURACY OF PROVIDER DIRECTORY INFORMA-**
 3 **TION.**

4 *(a) IN GENERAL.—Subpart II of part A of title XXVII*
 5 *of the Public Health Service Act (42 U.S.C. 300gg–11 et*
 6 *seq.), as amended by sections 301 and 302, is further*
 7 *amended by adding at the end the following:*

8 **“SEC. 2729C. PROTECTING PATIENTS AND IMPROVING THE**
 9 **ACCURACY OF PROVIDER DIRECTORY INFOR-**
 10 **MATION.**

11 *“(a) NETWORK STATUS OF PROVIDERS.—*

12 *“(1) IN GENERAL.—Beginning on the date that*
 13 *is one year after the date of enactment of this section,*
 14 *a group health plan or a health insurance issuer of-*
 15 *fering group or individual health insurance coverage*
 16 *shall—*

17 *“(A) establish business processes to ensure*
 18 *that all enrollees in such plan or coverage receive*
 19 *proof of a health care provider’s network status,*
 20 *based on what a plan or issuer knows or could*
 21 *reasonably know—*

22 *“(i) through a written electronic com-*
 23 *munication from the plan or issuer to the*
 24 *enrollee, as soon as practicable and not*
 25 *later than 1 business day after a telephone*

1 *inquiry is made by such enrollee for such*
 2 *information;*

3 “(ii) *through an oral confirmation,*
 4 *documented by such issuer or coverage, and*
 5 *kept in the enrollee’s file for a minimum of*
 6 *2 years; and*

7 “(iii) *in real-time through an online*
 8 *health care provider directory search tool*
 9 *maintained by the plan or issuer; and*

10 “(B) *include in any print directory a dis-*
 11 *closure that the information included in the di-*
 12 *rectory is accurate as of the date of the last data*
 13 *update and that enrollees or prospective enrollees*
 14 *should consult the group health plan or issuer’s*
 15 *electronic provider directory on its website or*
 16 *call a specified customer service telephone num-*
 17 *ber to obtain the most current provider directory*
 18 *information.*

19 “(2) *GROUP HEALTH PLAN AND HEALTH INSUR-*
 20 *ANCE ISSUER BUSINESS PROCESSES.—Beginning on*
 21 *the date that is one year after the date of enactment*
 22 *of the Lower Health Care Costs Act, a group health*
 23 *plan or a health insurance issuer offering group or*
 24 *individual health insurance coverage shall establish*
 25 *business processes to—*

1 “(A) verify and update, at least once every
 2 90 days, the provider directory information for
 3 all providers included in the online health care
 4 provider directory search tool described in para-
 5 graph (1)(A)(iii); and

6 “(B) remove any provider from such online
 7 directory search tool if such provider has not
 8 verified the directory information within the pre-
 9 vious 6 months or the plan or issuer has been
 10 unable to verify the provider’s network partici-
 11 pation.

12 “(b) *COST-SHARING LIMITATIONS.*—

13 “(1) *IN GENERAL.*—A group health plan or a
 14 health insurance issuer offering group or individual
 15 health insurance coverage shall not apply, and shall
 16 ensure that no provider applies cost-sharing to an en-
 17 rollee for treatment or services provided by a health
 18 care provider in excess of the normal cost-sharing ap-
 19 plied for in-network care (including any balance bill
 20 issued by the health care provider involved), if such
 21 enrollee, or health care provider referring such en-
 22 rollee, demonstrates (based on the electronic, written
 23 information described in subsection (a)(1)(A)(i), the
 24 oral confirmation described in subsection
 25 (a)(1)(A)(ii), or a copy of the online provider direc-

1 *tory described in subsection (a)(1)(A)(iii) on the date*
2 *the enrollee attempted to obtain the provider's net-*
3 *work status) that the enrollee relied on the informa-*
4 *tion described in subsection (a)(1), if the provider's*
5 *network status or directory information on such di-*
6 *rectory was incorrect at the time the treatment or*
7 *services involved was provided.*

8 *“(2) REFUNDS TO ENROLLEES.—If a health care*
9 *provider submits a bill to an enrollee in violation of*
10 *paragraph (1), and the enrollee pays such bill, the*
11 *provider shall reimburse the enrollee for the full*
12 *amount paid by the enrollee in excess of the in-net-*
13 *work cost-sharing amount for the treatment or serv-*
14 *ices involved, plus interest, at an interest rate deter-*
15 *mined by the Secretary.*

16 *“(c) PROVIDER BUSINESS PROCESSES.—A health care*
17 *provider shall have in place business processes to ensure the*
18 *timely provision of provider directory information to a*
19 *group health plan or a health insurance issuer offering*
20 *group or individual health insurance coverage to support*
21 *compliance by such plans or issuers with subsection (a)(1).*
22 *Such providers shall submit provider directory information*
23 *to a plan or issuers, at a minimum—*

1 “(1) *when the provider begins a network agree-*
 2 *ment with a plan or with an issuer with respect to*
 3 *certain coverage;*

4 “(2) *when the provider terminates a network*
 5 *agreement with a plan or with an issuer with respect*
 6 *to certain coverage;*

7 “(3) *when there are material changes to the con-*
 8 *tent of provider directory information described in*
 9 *subsection (a)(1); and*

10 “(4) *every 90 days throughout the duration of*
 11 *the network agreement with a plan or issuer.*

12 “(d) *ENFORCEMENT.—*

13 “(1) *IN GENERAL.—Subject to paragraph (2), a*
 14 *health care provider that violates a requirement under*
 15 *subsection (c) or takes actions that prevent a group*
 16 *health plan or health insurance issuer from com-*
 17 *plying with subsection (a)(1) or (b) shall be subject to*
 18 *a civil monetary penalty of not more than \$10,000*
 19 *for each act constituting such violation.*

20 “(2) *SAFE HARBOR.—The Secretary may waive*
 21 *the penalty described under paragraph (1) with re-*
 22 *spect to a health care provider that unknowingly vio-*
 23 *lates subsection (b)(1) with respect to an enrollee if*
 24 *such provider rescinds the bill involved and, if appli-*
 25 *cable, reimburses the enrollee within 30 days of the*

1 *date on which the provider billed the enrollee in viola-*
 2 *tion of such subsection.*

3 “(3) *PROCEDURE.*—*The provisions of section*
 4 *1128A of the Social Security Act, other than sub-*
 5 *sections (a) and (b) and the first sentence of sub-*
 6 *section (c)(1) of such section, shall apply to civil*
 7 *money penalties under this subsection in the same*
 8 *manner as such provisions apply to a penalty or pro-*
 9 *ceeding under section 1128A of the Social Security*
 10 *Act.*

11 “(e) *SAVINGS CLAUSE.*—*Nothing in this section shall*
 12 *prohibit a provider from requiring in the terms of a con-*
 13 *tract, or contract termination, with a group health plan*
 14 *or health insurance issuer—*

15 “(1) *that the plan or issuer remove, at the time*
 16 *of termination of such contract, the provider from a*
 17 *directory of the plan or issuer described in subsection*
 18 *(a)(1); or*

19 “(2) *that the plan or issuer bear financial re-*
 20 *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 Pub-
 17 *lic Health Service Act (42 U.S.C. 280g et seq.) is*
 18 *amended by adding at the end the following:*

19 **“SEC. 399V-7. TIMELY BILLS FOR PATIENTS.**

20 “(a) *IN GENERAL.*—The Secretary shall require—

21 “(1) *health care facilities, or in the case of prac-*
 22 *titioners providing services outside of such a facility,*
 23 *practitioners, to provide to patients a list of services*
 24 *rendered during the visit to such facility or practi-*
 25 *tioner, and, in the case of a facility, the name of the*

1 *provider for each such service, upon discharge or end*
 2 *of the visit or by postal or electronic communication*
 3 *as soon as practicable and not later than 5 calendar*
 4 *days after discharge or date of visit; and*

5 *“(2) health care facilities and practitioners to*
 6 *furnish all adjudicated bills to the patient as soon as*
 7 *practicable, but not later than 45 calendar days after*
 8 *discharge or date of visit.*

9 *“(b) PAYMENT AFTER BILLING.—No patient may be*
 10 *required to pay a bill for health care services any earlier*
 11 *than 35 days after the postmark date of a bill for such serv-*
 12 *ices.*

13 *“(c) EFFECT OF VIOLATION.—*

14 *“(1) NOTIFICATION AND REFUND REQUIRE-*
 15 *MENTS.—*

16 *“(A) PROVIDER LISTS.—If a facility or*
 17 *practitioner fails to provide a patient a list as*
 18 *required under subsection (a)(1), such facility or*
 19 *practitioner shall report such failure to the Sec-*
 20 *retary.*

21 *“(B) BILLING.—If a facility or practitioner*
 22 *bills a patient after the 45-calendar-day period*
 23 *described in subsection (a)(2), such facility or*
 24 *practitioner shall—*

1 “(i) report such bill to the Secretary;
2 and

3 “(ii) refund the patient for the full
4 amount paid in response to such bill with
5 interest, at a rate determined by the Sec-
6 retary.

7 “(2) CIVIL MONETARY PENALTIES.—

8 “(A) IN GENERAL.—The Secretary may im-
9 pose civil monetary penalties of up to \$10,000 a
10 day on any facility or practitioner that—

11 “(i) fails to provide a list required
12 under subsection (a)(1) more than 10 times,
13 beginning on the date of such tenth failure;

14 “(ii) submits more than 10 bills out-
15 side of the period described in subsection
16 (a)(2), beginning on the date on which such
17 facility or practitioner sends the tenth such
18 bill;

19 “(iii) fails to report to the Secretary
20 any failure to provide lists as required
21 under paragraph (1)(A), beginning on the
22 date that is 45 calendar days after dis-
23 charge or visit; or

24 “(iv) fails to send any bill as required
25 under subsection (a)(2), beginning on the

1 *date that is 45 calendar days after the date*
 2 *of discharge or visit, as applicable.*

3 “(B) *PROCEDURE.*—*The provisions of sec-*
 4 *tion 1128A of the Social Security Act, other than*
 5 *subsections (a) and (b) and the first sentence of*
 6 *subsection (c)(1) of such section, shall apply to*
 7 *civil money penalties under this subsection in*
 8 *the same manner as such provisions apply to a*
 9 *penalty or proceeding under section 1128A of the*
 10 *Social Security Act.*

11 “(3) *SAFE HARBOR.*—*The Secretary may exempt*
 12 *a practitioner or facility from the penalties under*
 13 *paragraph (2)(A) or extend the period of time speci-*
 14 *fied under subsection (a)(2) for compliance with such*
 15 *subsection if a practitioner or facility—*

16 “(A) *makes a good-faith attempt to send a*
 17 *bill within 30 days but is unable to do so be-*
 18 *cause of an incorrect address; or*

19 “(B) *experiences extenuating circumstances*
 20 *(as defined by the Secretary), such as a hurri-*
 21 *cane or cyberattack, that may reasonably delay*
 22 *delivery of a timely bill.”.*

23 (2) *RULEMAKING.*—*Not later than 1 year after*
 24 *the date of enactment of this Act, the Secretary shall*
 25 *promulgate final regulations to define the term “ex-*

1 *tenuating circumstance” for purposes of section*
 2 *399V–7(c)(3)(B) of the Public Health Service Act, as*
 3 *added by paragraph (1).*

4 *(b) GROUP HEALTH PLAN AND HEALTH INSURANCE*
 5 *ISSUER REQUIREMENTS.—Subpart II of part A of title*
 6 *XXVII of the Public Health Service Act (42 U.S.C. 300gg–*
 7 *11), as amended by section 304, is further amended by add-*
 8 *ing at the end the following:*

9 **“SEC. 2729D. TIMELY BILLS FOR PATIENTS.**

10 *“(a) IN GENERAL.—A group health plan or health in-*
 11 *surance issuer offering group or individual health insur-*
 12 *ance coverage shall have in place business practices with*
 13 *respect to in-network facilities and practitioners to ensure*
 14 *that claims are adjudicated in order to facilitate facility*
 15 *and practitioner compliance with the requirements under*
 16 *section 399V–7(a).*

17 *“(b) CLARIFICATION.—Nothing in subsection (a) pro-*
 18 *hibits a provider and a group health plan or health insur-*
 19 *ance issuer from establishing in a contract the timeline for*
 20 *submission by either party to the other party of billing in-*
 21 *formation, adjudication, sending of remittance information,*
 22 *or any other coordination required between the provider*
 23 *and the plan or issuer necessary for meeting the deadline*
 24 *described in section 399V–7(a)(2).”.*

1 (c) *EFFECTIVE DATE.*—*The amendments made by sub-*
 2 *sections (a) and (b) shall take effect 6 months after the date*
 3 *of enactment of this Act.*

4 **SEC. 306. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**
 5 **EFIT MANAGER SERVICES.**

6 *Subpart II of part A of title XXVII of the Public*
 7 *Health Service Act (42 U.S.C. 300gg–11 et seq.), as amend-*
 8 *ed by section 305(b), is further amended by adding at the*
 9 *end the following:*

10 **“SEC. 2729E. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**
 11 **EFIT MANAGER SERVICES.**

12 “(a) *IN GENERAL.*—*A group health plan or health in-*
 13 *surance issuer offering group health insurance coverage or*
 14 *an entity or subsidiary providing pharmacy benefits man-*
 15 *agement services shall not enter into a contract with a drug*
 16 *manufacturer, distributor, wholesaler, subcontractor, rebate*
 17 *aggregator, or any associated third party that limits the*
 18 *disclosure of information to plan sponsors in such a manner*
 19 *that prevents the plan or coverage, or an entity or sub-*
 20 *sidary providing pharmacy benefits management services*
 21 *on behalf of a plan or coverage from making the reports*
 22 *described in subsection (b).*

23 “(b) *REPORTS TO GROUP PLAN SPONSORS.*—

24 “(1) *IN GENERAL.*—*Beginning with the first*
 25 *plan year that begins after the date of enactment of*

1 *the Lower Health Care Costs Act, not less frequently*
2 *than once every 6 months, a health insurance issuer*
3 *offering group health insurance coverage or an entity*
4 *providing pharmacy benefits management services on*
5 *behalf of a group health plan shall submit to the plan*
6 *sponsor (as defined in section 3(16)(B) of the Em-*
7 *ployee Retirement Income Security Act of 1974) of*
8 *such group health plan or health insurance coverage*
9 *a report in accordance with this subsection and make*
10 *such report available to the plan sponsor in a ma-*
11 *chine-readable format. Each such report shall include,*
12 *with respect to the applicable group health plan or*
13 *health insurance coverage—*

14 “(A) information collected from drug manu-
15 facturers by such issuer or entity on the total
16 amount of copayment assistance dollars paid, or
17 copayment cards applied, that were funded by
18 the drug manufacturer with respect to the enroll-
19 ees in such plan or coverage;

20 “(B) a list of each covered drug dispensed
21 during the reporting period, including, with re-
22 spect to each such drug during the reporting pe-
23 riod—

24 “(i) the brand name, chemical entity,
25 and National Drug Code;

1 “(ii) the number of enrollees for whom
2 the drug was filled during the plan year,
3 the total number of prescription fills for the
4 drug (including original prescriptions and
5 refills), and the total number of dosage
6 units of the drug dispensed across the plan
7 year, including whether the dispensing
8 channel was by retail, mail order, or spe-
9 cialty pharmacy;

10 “(iii) the wholesale acquisition cost,
11 listed as cost per days supply and cost per
12 pill, or in the case of a drug in another
13 form, per dose;

14 “(iv) the total out-of-pocket spending
15 by enrollees on such drug, including enrollee
16 spending through copayments, coinsurance,
17 and deductibles;

18 “(v) for any drug for which gross
19 spending of the group health plan or health
20 insurance coverage exceeded \$10,000 during
21 the reporting period—

22 “(I) a list of all other available
23 drugs in the same therapeutic category
24 or class, including brand name drugs
25 and biological products and generic

1 *drugs or biosimilar biological products*
2 *that are in the same therapeutic cat-*
3 *egory or class; and*

4 “(II) *the rationale for preferred*
5 *formulary placement of a particular*
6 *drug or drugs in that therapeutic cat-*
7 *egory or class;*

8 “(C) *a list of each therapeutic category or*
9 *class of drugs that were dispensed under the*
10 *health plan or health insurance coverage during*
11 *the reporting period, and, with respect to each*
12 *such therapeutic category or class of drugs, dur-*
13 *ing the reporting period—*

14 “(i) *total gross spending by the plan,*
15 *before manufacturer rebates, fees, or other*
16 *manufacturer remuneration;*

17 “(ii) *the number of enrollees who filled*
18 *a prescription for a drug in that category*
19 *or class;*

20 “(iii) *if applicable to that category or*
21 *class, a description of the formulary tiers*
22 *and utilization mechanisms (such as prior*
23 *authorization or step therapy) employed for*
24 *drugs in that category or class;*

1 “(iv) the total out-of-pocket spending
 2 by enrollees, including enrollee spending
 3 through copayments, coinsurance, and
 4 deductibles; and

5 “(v) for each therapeutic category or
 6 class under which 3 or more drugs are in-
 7 cluded on the formulary of such plan or cov-
 8 erage—

9 “(I) the amount received, or ex-
 10 pected to be received, from drug manu-
 11 facturers in rebates, fees, alternative
 12 discounts, or other remuneration—

13 “(aa) to be paid by drug
 14 manufacturers for claims incurred
 15 during the reporting period; or

16 “(bb) that is related to utili-
 17 zation of drugs, in such thera-
 18 peutic category or class;

19 “(II) the total net spending, after
 20 deducting rebates, price concessions, al-
 21 ternative discounts or other remunera-
 22 tion from drug manufacturers, by the
 23 health plan or health insurance cov-
 24 erage on that category or class of
 25 drugs; and

1 “(III) the net price per course of
2 treatment or 30-day supply incurred
3 by the health plan or health insurance
4 coverage and its enrollees, after manu-
5 facturer rebates, fees, and other remu-
6 neration for drugs dispensed within
7 such therapeutic category or class dur-
8 ing the reporting period;

9 “(D) total gross spending on prescription
10 drugs by the plan or coverage during the report-
11 ing period, before rebates and other manufac-
12 turer fees or remuneration;

13 “(E) total amount received, or expected to
14 be received, by the health plan or health insur-
15 ance coverage in drug manufacturer rebates, fees,
16 alternative discounts, and all other remuneration
17 received from the manufacturer or any third
18 party, other than the plan sponsor, related to
19 utilization of drug or drug spending under that
20 health plan or health insurance coverage during
21 the reporting period;

22 “(F) the total net spending on prescription
23 drugs by the health plan or health insurance cov-
24 erage during the reporting period; and

1 “(G) amounts paid directly or indirectly in
 2 rebates, fees, or any other type of remuneration
 3 to brokers, consultants, advisors, or any other in-
 4 dividual or firm who referred the group health
 5 plan’s or health insurance issuer’s business to the
 6 pharmacy benefit manager.

7 “(2) *PRIVACY REQUIREMENTS.*—Health insur-
 8 ance issuers offering group health insurance coverage
 9 and entities providing pharmacy benefits manage-
 10 ment services on behalf of a group health plan shall
 11 provide information under paragraph (1) in a man-
 12 ner consistent with the privacy, security, and breach
 13 notification regulations promulgated under section
 14 264(c) of the Health Insurance Portability and Ac-
 15 countability Act of 1996 (or successor regulations),
 16 and shall restrict the use and disclosure of such infor-
 17 mation according to such privacy regulations.

18 “(3) *DISCLOSURE AND REDISCLOSURE.*—

19 “(A) *LIMITATION TO BUSINESS ASSOCI-*
 20 *ATES.*—A group health plan receiving a report
 21 under paragraph (1) may disclose such informa-
 22 tion only to business associates of such plan as
 23 defined in section 160.103 of title 45, Code of
 24 Federal Regulations (or successor regulations).

1 “(B) *CLARIFICATION REGARDING PUBLIC*
2 *DISCLOSURE OF INFORMATION.*—*Nothing in this*
3 *section prevents a health insurance issuer offer-*
4 *ing group health insurance coverage or an entity*
5 *providing pharmacy benefits management serv-*
6 *ices on behalf of a group health plan from plac-*
7 *ing reasonable restrictions on the public disclo-*
8 *sure of the information contained in a report de-*
9 *scribed in paragraph (1), except that such issuer*
10 *or entity may not restrict disclosure of such re-*
11 *port to governmental agencies pursuant to an in-*
12 *vestigation or enforcement action.*

13 “(C) *LIMITED FORM OF REPORT.*—*The Sec-*
14 *retary shall define through rulemaking a limited*
15 *form of the report under paragraph (1) required*
16 *of plan sponsors who are drug manufacturers,*
17 *drug wholesalers, or other direct participants in*
18 *the drug supply chain, in order to prevent anti-*
19 *competitive behavior.*

20 “(c) *LIMITATIONS ON SPREAD PRICING.*—

21 “(1) *PRESCRIPTION DRUG TRANSACTIONS WITH*
22 *PHARMACIES INDEPENDENT OF THE ISSUER OR*
23 *PHARMACY BENEFITS MANAGER.*—*If the pharmacy*
24 *that dispenses a prescription drug to an enrollee in*
25 *a group health plan or group or individual health in-*

1 *surance coverage is not wholly or partially-owned by*
 2 *such plan, such issuer, or an entity providing phar-*
 3 *macy benefit management services under such plan or*
 4 *coverage, such plan, issuer, or entity shall not charge*
 5 *the plan, issuer, or enrollee a price for such prescrip-*
 6 *tion drug that exceeds the price paid to the phar-*
 7 *macy, excluding penalties paid by pharmacies to such*
 8 *plan, issuer, or entity.*

9 *“(2) INTRA-COMPANY PRESCRIPTION DRUG*
 10 *TRANSACTIONS.—If the mail order, specialty, or retail*
 11 *pharmacy that dispenses a prescription drug to an*
 12 *enrollee in a group health plan or health insurance*
 13 *coverage is wholly or partially owned by, and submits*
 14 *claims to, such health insurance issuer or an entity*
 15 *providing pharmacy benefit management services*
 16 *under a group health plan or group or individual*
 17 *health insurance coverage, the price charged for such*
 18 *drug by such pharmacy to such group health plan or*
 19 *health insurance issuer offering group or individual*
 20 *health insurance coverage may not exceed the lesser*
 21 *of—*

22 *“(A) the amount paid to the pharmacy for*
 23 *acquisition of the drug; or*

24 *“(B) the median price charged to the group*
 25 *health plan or health insurance issuer when the*

1 *same drug is dispensed to enrollees in the plan*
2 *or coverage by other similarly-situated phar-*
3 *macies not wholly or partially owned by the*
4 *health insurance issuer or entity providing phar-*
5 *macy benefits management services, as described*
6 *in paragraph (1).*

7 “(3) *SUPPLEMENTARY REPORTING FOR INTRA-*
8 *COMPANY PRESCRIPTION DRUG TRANSACTIONS.—A*
9 *health insurance issuer of group health insurance cov-*
10 *erage or an entity providing pharmacy benefits man-*
11 *agement services under a group health plan or group*
12 *health insurance coverage that conducts transactions*
13 *with a wholly or partially-owned pharmacy, as de-*
14 *scribed in paragraph (2), shall submit, together with*
15 *the report under subsection (b), a supplementary re-*
16 *port every 6 months to the plan sponsor that in-*
17 *cludes—*

18 “(A) *an explanation of any benefit design*
19 *parameters that encourage enrollees in the plan*
20 *or coverage to fill prescriptions at mail order,*
21 *specialty, or retail pharmacies that are wholly or*
22 *partially-owned by that issuer or entity;*

23 “(B) *the percentage of total prescriptions*
24 *charged to the plan, coverage, or enrollees in the*
25 *plan or coverage, that were dispensed by mail*

1 *order, specialty, or retail pharmacies that are*
2 *wholly or partially-owned by the issuer or entity*
3 *providing pharmacy benefits management serv-*
4 *ices; and*

5 *“(C) a list of all drugs dispensed by such*
6 *wholly or partially-owned pharmacy and*
7 *charged to the plan or coverage, or enrollees of*
8 *the plan or coverage, during the applicable quar-*
9 *ter, and, with respect to each drug—*

10 *“(i) the amount charged per course of*
11 *treatment or 30-day supply with respect to*
12 *enrollees in the plan or coverage, including*
13 *amounts charged to the plan or coverage*
14 *and amounts charged to the enrollee;*

15 *“(ii) the median amount charged to the*
16 *plan or coverage, per course of treatment or*
17 *30-day supply, including amounts paid by*
18 *the enrollee, when the same drug is dis-*
19 *persed by other pharmacies that are not*
20 *wholly or partially-owned by the issuer or*
21 *entity and that are included in the phar-*
22 *macy network of that plan or coverage;*

23 *“(iii) the interquartile range of the*
24 *costs, per course of treatment or 30-day sup-*
25 *ply, including amounts paid by the enrollee,*

1 *when the same drug is dispensed by other*
 2 *pharmacies that are not wholly or par-*
 3 *tially-owned by the issuer or entity and*
 4 *that are included in the pharmacy network*
 5 *of that plan or coverage;*

6 “(iv) *the lowest cost per course of treat-*
 7 *ment or 30-day supply, for such drug, in-*
 8 *cluding amounts charged to the plan or*
 9 *issuer and enrollee, that is available from*
 10 *any pharmacy included in the network of*
 11 *the plan or coverage.*

12 “(d) *FULL REBATE PASS-THROUGH TO PLAN.—*

13 “(1) *IN GENERAL.—A pharmacy benefits man-*
 14 *ager, a third-party administrator of a group health*
 15 *plan, a health insurance issuer offering group health*
 16 *insurance coverage, or an entity providing pharmacy*
 17 *benefits management services under such health plan*
 18 *or health insurance coverage shall remit 100 percent*
 19 *of rebates, fees, alternative discounts, and all other re-*
 20 *muneration received from a pharmaceutical manufac-*
 21 *turer, distributor or any other third party, that are*
 22 *related to utilization of drugs under such health plan*
 23 *or health insurance coverage, to the group health*
 24 *plan.*

1 “(2) *FORM AND MANNER OF REMITTANCE.*—Such
2 rebates, fees, alternative discounts, and other remun-
3 eration shall be—

4 “(A) *remitted to the group health plan in a*
5 *timely fashion after the period for which such re-*
6 *bates, fees, or other remuneration is calculated,*
7 *and in no case later than 90 days after the end*
8 *of such period;*

9 “(B) *fully disclosed and enumerated to the*
10 *group health plan sponsor, as described in (b)(1);*

11 “(C) *available for audit by the plan spon-*
12 *sor, or a third-party designated by a plan spon-*
13 *sor no less than once per plan year; and*

14 “(D) *returned to the issuer or entity pro-*
15 *viding pharmaceutical benefit management serv-*
16 *ices by the group health plan if audits by such*
17 *issuer or entity indicate that the amounts re-*
18 *ceived are incorrect after such amounts have been*
19 *paid to the group health plan.*

20 “(3) *AUDIT OF REBATE CONTRACTS.*—A phar-
21 *macy benefits manager, a third-party administrator*
22 *of a group health plan, a health insurance issuer of-*
23 *fering group health insurance coverage, or an entity*
24 *providing pharmacy benefits management services*
25 *under such health plan or health insurance coverage*

1 *shall make rebate contracts with drug manufacturers*
 2 *available for audit by such plan sponsor or des-*
 3 *ignated third-party, subject to confidentiality agree-*
 4 *ments to prevent re-disclosure of such contracts.*

5 “(e) *ENFORCEMENT.*—

6 “(1) *IN GENERAL.*—*The Secretary, in consulta-*
 7 *tion with the Secretary of Labor and the Secretary of*
 8 *the Treasury, shall enforce this section.*

9 “(2) *FAILURE TO PROVIDE TIMELY INFORMA-*
 10 *TION.*—*A health insurance issuer or an entity pro-*
 11 *viding pharmacy benefit management services that*
 12 *violates subsection (a), fails to provide information*
 13 *required under subsection (b), engages in spread pric-*
 14 *ing as defined in subsection (c), or fails to comply*
 15 *with the requirements of subsection (d), or a drug*
 16 *manufacturer that fails to provide information under*
 17 *subsection (b)(1)(A), in a timely manner shall be sub-*
 18 *ject to a civil monetary penalty in the amount of*
 19 *\$10,000 for each day during which such violation*
 20 *continues or such information is not disclosed or re-*
 21 *ported.*

22 “(3) *FALSE INFORMATION.*—*A health insurance*
 23 *issuer, entity providing pharmacy benefit manage-*
 24 *ment services, or drug manufacturer that knowingly*
 25 *provides false information under this section shall be*

1 *subject to a civil money penalty in an amount not to*
 2 *exceed \$100,000 for each item of false information.*
 3 *Such civil money penalty shall be in addition to other*
 4 *penalties as may be prescribed by law.*

5 *“(4) PROCEDURE.—The provisions of section*
 6 *1128A of the Social Security Act, other than sub-*
 7 *section (a) and (b) and the first sentence of subsection*
 8 *(c)(1) of such section shall apply to civil monetary*
 9 *penalties under this subsection in the same manner as*
 10 *such provisions apply to a penalty or proceeding*
 11 *under section 1128A of the Social Security Act.*

12 *“(5) SAFE HARBOR.—The Secretary may waive*
 13 *penalties under paragraph (2), or extend the period*
 14 *of time for compliance with a requirement of this sec-*
 15 *tion, for an entity in violation of this section that has*
 16 *made a good-faith effort to comply with this section.*

17 *“(f) RULE OF CONSTRUCTION.—Nothing in this sec-*
 18 *tion shall be construed to prohibit payments to entities of-*
 19 *fering pharmacy benefits management services for bona fide*
 20 *services using a fee structure not contemplated by this sec-*
 21 *tion, provided that such fees are transparent to group health*
 22 *plans and health insurance issuers.*

23 *“(g) DEFINITIONS.—In this section—*

24 *“(1) the term ‘similarly situated pharmacy’*
 25 *means, with respect to a particular pharmacy, an-*

1 *other pharmacy that is approximately the same size*
 2 *(as measured by the number of prescription drugs dis-*
 3 *persed), and that serves patients in the same geo-*
 4 *graphical area, whether through physical locations or*
 5 *mail order; and*

6 *“(2) the term ‘wholesale acquisition cost’ has the*
 7 *meaning given such term in sectionb1847A(c)(6)(B)*
 8 *of the Social Security Act.”.*

9 **SEC. 307. GOVERNMENT ACCOUNTABILITY OFFICE STUDY**
 10 **ON PROFIT- AND REVENUE-SHARING IN**
 11 **HEALTH CARE.**

12 *(a) STUDY.—Not later than 1 year after the date of*
 13 *enactment of this Act, the Comptroller General of the United*
 14 *States shall conduct a study to—*

15 *(1) describe what is known about profit- and*
 16 *revenue-sharing relationships in the commercial*
 17 *health care markets, including those relationships*
 18 *that—*

19 *(A) involve one or more—*

20 *(i) physician groups that practice*
 21 *within a hospital included in the profit- or*
 22 *revenue-sharing relationship, or refer pa-*
 23 *tients to such hospital;*

1 (ii) laboratory, radiology, or pharmacy
 2 services that are delivered to privately in-
 3 sured patients of such hospital;

4 (iii) surgical services;

5 (iv) hospitals or group purchasing or-
 6 ganizations; or

7 (v) rehabilitation or physical therapy
 8 facilities or services; and

9 (B) include revenue- or profit-sharing
 10 whether through a joint venture, management or
 11 professional services agreement, or other form of
 12 gain-sharing contract;

13 (2) describe Federal oversight of such relation-
 14 ships, including authorities of the Department of
 15 Health and Human Services and the Federal Trade
 16 Commission to review such relationships and their
 17 potential to increase costs for patients, and identify
 18 limitations in such oversight; and

19 (3) as appropriate, make recommendations to
 20 improve Federal oversight of such relationships.

21 (b) *REPORT*.—Not later than 1 year after the date of
 22 enactment of this Act, the Comptroller General of the United
 23 States shall prepare and submit a report on the study con-
 24 ducted under subsection (a) to the Committee on Health,
 25 Education, Labor, and Pensions of the Senate and the Com-

1 *mittee on Education and Labor and Committee on Energy*
 2 *and Commerce of the House of Representatives.*

3 **SEC. 308. DISCLOSURE OF DIRECT AND INDIRECT COM-**
 4 **PENSATION FOR BROKERS AND CONSULT-**
 5 **ANTS TO EMPLOYER-SPONSORED HEALTH**
 6 **PLANS AND ENROLLEES IN PLANS ON THE IN-**
 7 **DIVIDUAL MARKET.**

8 *(a) GROUP HEALTH PLANS.—Section 408(b)(2) of the*
 9 *Employee Retirement Income Security Act of 1974 (29*
 10 *U.S.C. 1108(b)(2)) is amended—*

11 *(1) by striking “(2) Contracting or making” and*
 12 *inserting “(2)(A) Contracting or making”; and*

13 *(2) by adding at the end the following:*

14 *“(B)(i) No contract or arrangement for services*
 15 *between a covered plan and a covered service pro-*
 16 *vider, and no extension or renewal of such a contract*
 17 *or arrangement, is reasonable within the meaning of*
 18 *this paragraph unless the requirements of this clause*
 19 *are met.*

20 *“(ii)(I) For purposes of this subparagraph:*

21 *“(aa) The term ‘covered plan’ means a*
 22 *group health plan as defined section 733(a).*

23 *“(bb) The term ‘covered service provider’*
 24 *means a service provider that enters into a con-*
 25 *tract or arrangement with the covered plan and*

1 *reasonably expects \$1,000 (or such amount as the*
2 *Secretary may establish in regulations to ac-*
3 *count for inflation since the date of enactment of*
4 *the Lower Health Care Costs Act, as appro-*
5 *priate) or more in compensation, direct or indi-*
6 *rect, to be received in connection with providing*
7 *one or more of the following services, pursuant to*
8 *the contract or arrangement, regardless of wheth-*
9 *er such services will be performed, or such com-*
10 *penetration received, by the covered service pro-*
11 *vider, an affiliate, or a subcontractor:*

12 *“(AA) Brokerage services, for which the*
13 *covered service provider, an affiliate, or a*
14 *subcontractor reasonably expects to receive*
15 *indirect compensation or direct compensa-*
16 *tion described in item (dd), provided to a*
17 *covered plan with respect to selection of in-*
18 *surance products (including vision and den-*
19 *tal), recordkeeping services, medical man-*
20 *agement vendor, benefits administration*
21 *(including vision and dental), stop-loss in-*
22 *surance, pharmacy benefit management*
23 *services, wellness services, transparency*
24 *tools and vendors, group purchasing organi-*
25 *zation preferred vendor panels, disease*

1 management vendors and products, compli-
2 ance services, employee assistance programs,
3 or third party administration services.

4 “(BB) Consulting, for which the cov-
5 ered service provider, an affiliate, or a sub-
6 contractor reasonably expects to receive in-
7 direct compensation or direct compensation
8 described in item (dd), related to the devel-
9 opment or implementation of plan design,
10 insurance or insurance product selection
11 (including vision and dental), record-
12 keeping, medical management, benefits ad-
13 ministration selection (including vision and
14 dental), stop-loss insurance, pharmacy ben-
15 efit management services, wellness design
16 and management services, transparency
17 tools, group purchasing organization agree-
18 ments and services, participation in and
19 services from preferred vendor panels, dis-
20 ease management, compliance services, em-
21 ployee assistance programs, or third party
22 administration services.

23 “(cc) The term ‘affiliate’, with respect to a
24 covered service provider, means an entity that
25 directly or indirectly (through one or more inter-

1 *mediaries) controls, is controlled by, or is under*
2 *common control with, such provider, or is an of-*
3 *ficer, director, or employee of, or partner in,*
4 *such provider.*

5 *“(dd)(AA) The term ‘compensation’ means*
6 *anything of monetary value, but does not include*
7 *non-monetary compensation valued at \$250 (or*
8 *such amount as the Secretary may establish in*
9 *regulations to account for inflation since the date*
10 *of enactment of the Lower Health Care Costs Act,*
11 *as appropriate) or less, in the aggregate, during*
12 *the term of the contract or arrangement.*

13 *“(BB) The term ‘direct compensation’*
14 *means compensation received directly from a*
15 *covered plan.*

16 *“(CC) The term ‘indirect compensation’*
17 *means compensation received from any source*
18 *other than the covered plan, the plan sponsor, the*
19 *covered service provider, or an affiliate. Com-*
20 *ensation received from a subcontractor is indi-*
21 *rect compensation, unless it is received in con-*
22 *nection with services performed under a contract*
23 *or arrangement with a subcontractor.*

24 *“(ee) The term ‘responsible plan fiduciary’*
25 *means a fiduciary with authority to cause the*

1 *covered plan to enter into, or extend or renew,*
2 *the contract or arrangement.*

3 “(ff) *The term ‘subcontractor’ means any*
4 *person or entity (or an affiliate of such person*
5 *or entity) that is not an affiliate of the covered*
6 *service provider and that, pursuant to a contract*
7 *or arrangement with the covered service provider*
8 *or an affiliate, reasonably expects to receive*
9 *\$1,000 (or such amount as the Secretary may es-*
10 *tablish in regulations to account for inflation*
11 *since the date of enactment of the Lower Health*
12 *Care Costs Act, as appropriate) or more in com-*
13 *ensation for performing one or more services*
14 *described in item (bb) under a contract or ar-*
15 *rangement with the covered plan.*

16 “(II) *For purposes of this subparagraph, a de-*
17 *scription of compensation or cost may be expressed as*
18 *a monetary amount, formula, or a per capita charge*
19 *for each enrollee or, if the compensation or cost can-*
20 *not reasonably be expressed in such terms, by any*
21 *other reasonable method, including a disclosure that*
22 *additional compensation may be earned but may not*
23 *be calculated at the time of contract if such a disclo-*
24 *sure includes a description of the circumstances under*
25 *which the additional compensation may be earned*

1 *and a reasonable and good faith estimate if the cov-*
 2 *ered service provider cannot otherwise readily describe*
 3 *compensation or cost and explains the methodology*
 4 *and assumptions used to prepare such estimate. Any*
 5 *such description shall contain sufficient information*
 6 *to permit evaluation of the reasonableness of the com-*
 7 *penetration or cost.*

8 *“(III) No person or entity is a ‘covered service*
 9 *provider’ within the meaning of subclause (I)(bb) sole-*
 10 *ly on the basis of providing services as an affiliate or*
 11 *a subcontractor that is performing one or more of the*
 12 *services described in subitem (AA) or (BB) of such*
 13 *subclause under the contract or arrangement with the*
 14 *covered plan.*

15 *“(iii) A covered service provider shall disclose to*
 16 *a responsible plan fiduciary, in writing, the fol-*
 17 *lowing:*

18 *“(I) A description of the services to be pro-*
 19 *vided to the covered plan pursuant to the con-*
 20 *tract or arrangement.*

21 *“(II) If applicable, a statement that the cov-*
 22 *ered service provider, an affiliate, or a subcon-*
 23 *tractor will provide, or reasonably expects to*
 24 *provide, services pursuant to the contract or ar-*

1 *rangement directly to the covered plan as a fidu-*
 2 *ciary (within the meaning of section 3(21)).*

3 *“(III) A description of all direct compensa-*
 4 *tion, either in the aggregate or by service, that*
 5 *the covered service provider, an affiliate, or a*
 6 *subcontractor reasonably expects to receive in*
 7 *connection with the services described in sub-*
 8 *clause (I).*

9 *“(IV)(aa) A description of all indirect com-*
 10 *penetration that the covered service provider, an*
 11 *affiliate, or a subcontractor reasonably expects to*
 12 *receive in connection with the services described*
 13 *in subclause (I)—*

14 *“(AA) including compensation from a*
 15 *vendor to a brokerage firm based on a struc-*
 16 *ture of incentives not solely related to the*
 17 *contract with the covered plan; and*

18 *“(BB) not including compensation re-*
 19 *ceived by an employee from an employer on*
 20 *account of work performed by the employee.*

21 *“(bb) A description of the arrangement be-*
 22 *tween the payer and the covered service provider,*
 23 *an affiliate, or a subcontractor, as applicable,*
 24 *pursuant to which such indirect compensation is*
 25 *paid.*

1 “(cc) *Identification of the services for which*
2 *the indirect compensation will be received, if ap-*
3 *plicable.*

4 “(dd) *Identification of the payer of the indi-*
5 *rect compensation.*

6 “(V) *A description of any compensation*
7 *that will be paid among the covered service pro-*
8 *vider, an affiliate, or a subcontractor, in connec-*
9 *tion with the services described in subclause (I)*
10 *if such compensation is set on a transaction*
11 *basis (such as commissions, finder’s fees, or other*
12 *similar incentive compensation based on business*
13 *placed or retained), including identification of*
14 *the services for which such compensation will be*
15 *paid and identification of the payers and recipi-*
16 *ents of such compensation (including the status*
17 *of a payer or recipient as an affiliate or a sub-*
18 *contractor), regardless of whether such compensa-*
19 *tion also is disclosed pursuant to subclause (III)*
20 *or (IV).*

21 “(VI) *A description of any compensation*
22 *that the covered service provider, an affiliate, or*
23 *a subcontractor reasonably expects to receive in*
24 *connection with termination of the contract or*
25 *arrangement, and how any prepaid amounts*

1 *will be calculated and refunded upon such termi-*
2 *nation.*

3 “(iv) *A covered service provider shall disclose to*
4 *a responsible plan fiduciary, in writing a description*
5 *of the manner in which the compensation described in*
6 *clause (iii), as applicable, will be received.*

7 “(v)(I) *A covered service provider shall disclose*
8 *the information required under clauses (iii) and (iv)*
9 *to the responsible plan fiduciary not later than the*
10 *date that is reasonably in advance of the date on*
11 *which the contract or arrangement is entered into,*
12 *and extended or renewed.*

13 “(II) *A covered service provider shall disclose*
14 *any change to the information required under clause*
15 *(iii) and (iv) as soon as practicable, but not later*
16 *than 60 days from the date on which the covered serv-*
17 *ice provider is informed of such change, unless such*
18 *disclosure is precluded due to extraordinary cir-*
19 *cumstances beyond the covered service provider’s con-*
20 *trol, in which case the information shall be disclosed*
21 *as soon as practicable.*

22 “(vi)(I) *Upon the written request of the respon-*
23 *sible plan fiduciary or covered plan administrator, a*
24 *covered service provider shall furnish any other infor-*
25 *mation relating to the compensation received in con-*

1 *nection with the contract or arrangement that is re-*
2 *quired for the covered plan to comply with the report-*
3 *ing and disclosure requirements under this Act.*

4 *“(II) The covered service provider shall disclose*
5 *the information required under clause (iii)(I) reason-*
6 *ably in advance of the date upon which such respon-*
7 *sible plan fiduciary or covered plan administrator*
8 *states that it is required to comply with the applica-*
9 *ble reporting or disclosure requirement, unless such*
10 *disclosure is precluded due to extraordinary cir-*
11 *cumstances beyond the covered service provider’s con-*
12 *trol, in which case the information shall be disclosed*
13 *as soon as practicable.*

14 *“(vii) No contract or arrangement will fail to be*
15 *reasonable under this subparagraph solely because the*
16 *covered service provider, acting in good faith and*
17 *with reasonable diligence, makes an error or omission*
18 *in disclosing the information required pursuant to*
19 *clause (iii) (or a change to such information disclosed*
20 *pursuant to clause (v)(II)) or clause (vi), provided*
21 *that the covered service provider discloses the correct*
22 *information to the responsible plan fiduciary as soon*
23 *as practicable, but not later than 30 days from the*
24 *date on which the covered service provider knows of*
25 *such error or omission.*

1 “(viii)(I) Pursuant to subsection (a), subpara-
2 graphs (C) and (D) of section 406(a)(1) shall not
3 apply to a responsible plan fiduciary, notwith-
4 standing any failure by a covered service provider to
5 disclose information required under clause (iii), if the
6 following conditions are met:

7 “(aa) The responsible plan fiduciary did
8 not know that the covered service provider failed
9 or would fail to make required disclosures and
10 reasonably believed that the covered service pro-
11 vider disclosed the information required to be
12 disclosed.

13 “(bb) The responsible plan fiduciary, upon
14 discovering that the covered service provider
15 failed to disclose the required information, re-
16 quests in writing that the covered service pro-
17 vider furnish such information.

18 “(cc) If the covered service provider fails to
19 comply with a written request described in sub-
20 clause (II) within 90 days of the request, the re-
21 sponsible plan fiduciary notifies the Secretary of
22 the covered service provider’s failure, in accord-
23 ance with subclauses (II) and (III).

24 “(II) A notice described in subclause (I)(cc) shall
25 contain—

1 “(aa) the name of the covered plan;

2 “(bb) the plan number used for the annual
3 report on the covered plan;

4 “(cc) the plan sponsor’s name, address, and
5 employer identification number;

6 “(dd) the name, address, and telephone
7 number of the responsible plan fiduciary;

8 “(ee) the name, address, phone number,
9 and, if known, employer identification number of
10 the covered service provider;

11 “(ff) a description of the services provided
12 to the covered plan;

13 “(gg) a description of the information that
14 the covered service provider failed to disclose;

15 “(hh) the date on which such information
16 was requested in writing from the covered service
17 provider; and

18 “(ii) a statement as to whether the covered
19 service provider continues to provide services to
20 the plan.

21 “(III) A notice described in subclause (I)(cc)
22 shall be filed with the Department not later than 30
23 days following the earlier of—

1 “(aa) *The covered service provider’s refusal*
 2 *to furnish the information requested by the writ-*
 3 *ten request described in subclause (I)(bb); or*

4 “(bb) *90 days after the written request re-*
 5 *ferred to in subclause (I)(cc) is made.*

6 “(IV) *If the covered service provider fails to com-*
 7 *ply with the written request under subclause (I)(bb)*
 8 *within 90 days of such request, the responsible plan*
 9 *fiduciary shall determine whether to terminate or*
 10 *continue the contract or arrangement under section*
 11 *404. If the requested information relates to future*
 12 *services and is not disclosed promptly after the end*
 13 *of the 90-day period, the responsible plan fiduciary*
 14 *shall terminate the contract or arrangement as expe-*
 15 *ditiously as possible, consistent with such duty of*
 16 *prudence.*

17 “(ix) *Nothing in this subparagraph shall be con-*
 18 *strued to supersede any provision of State law that*
 19 *governs disclosures by parties that provide the services*
 20 *described in this section, except to the extent that such*
 21 *law prevents the application of a requirement of this*
 22 *section.”.*

23 (b) *APPLICABILITY OF EXISTING REGULATIONS.—*
 24 *Nothing in the amendments made by subsection (a) shall*
 25 *be construed to affect the applicability of section 2550.408b—*

1 *2 of title 29, Code of Federal Regulations (or any successor*
 2 *regulations), with respect to any applicable entity other*
 3 *than a covered plan or a covered service provider (as de-*
 4 *finied in section 408(b)(2)(B)(ii) of the Employee Retire-*
 5 *ment Income Security Act of 1974, as amended by sub-*
 6 *section (a)).*

7 *(c) INDIVIDUAL MARKET COVERAGE.—Subpart 1 of*
 8 *part B of title XXVII of the Public Health Service Act (42*
 9 *U.S.C. 300gg–41 et seq.) is amended by adding at the end*
 10 *the following:*

11 **“SEC. 2746. DISCLOSURE TO ENROLLEES OF INDIVIDUAL**
 12 **MARKET COVERAGE.**

13 *“(a) IN GENERAL.—A health insurance issuer offering*
 14 *individual health insurance coverage shall make disclosures*
 15 *to enrollees in such coverage, as described in subsection (b),*
 16 *and reports to the Secretary, as described in subsection (c),*
 17 *regarding direct or indirect compensation provided to an*
 18 *agent or broker associated with enrolling individuals in*
 19 *such coverage.*

20 *“(b) DISCLOSURE.—A health insurance issuer de-*
 21 *scribed in subsection (a) shall disclose to an enrollee the*
 22 *amount of direct or indirect compensation provided to an*
 23 *agent or broker for services provided by such agent or broker*
 24 *associated with plan selection and enrollment. Such disclo-*
 25 *sure shall be—*

1 “(1) made prior to the individual finalizing
2 plan selection; and

3 “(2) included on any documentation confirming
4 the individual’s enrollment.

5 “(c) *REPORTING*.—A health insurance issuer described
6 in subsection (a) shall annually report to the Secretary,
7 prior to the beginning of open enrollment, any direct or
8 indirect compensation provided to an agent or broker asso-
9 ciated with enrolling individuals in such coverage.

10 “(d) *RULEMAKING*.—Not later than 1 year after the
11 date of enactment of the Lower Health Care Costs Act, the
12 Secretary shall finalize, through notice-and-comment rule-
13 making, the form and manner in which issuers described
14 in subsection (a) are required to make the disclosures de-
15 scribed in subsection (b) and the reports described in sub-
16 section (c).”.

17 “(d) *TRANSITION RULE*.—No contract executed prior to
18 the effective date described in subsection (e) by a group
19 health plan subject to the requirements of section
20 408(b)(2)(B) of the Employee Retirement Income Security
21 Act of 1974 (as amended by subsection (a)) or by a health
22 insurance issuer subject to the requirements of section 2746
23 of the Public Health Service Act (as added by subsection
24 (c)) shall be subject to the requirements of such section 408(
25 b)(2)(B) or such section 2746, as applicable.

1 (e) *EFFECTIVE DATE.*—The amendments made by sub-
 2 sections (a) and (c) shall take effect 2 years after the date
 3 of enactment of this Act.

4 **SEC. 309. ENSURING ENROLLEE ACCESS TO COST-SHARING**
 5 **INFORMATION.**

6 (a) *IN GENERAL.*—Subpart II of part A of title XXVII
 7 of the Public Health Service Act (42 U.S.C. 300gg–11 et
 8 seq.), as amended by section 306, is further amended by
 9 adding at the end the following:

10 **“SEC. 2729F. PROVISION OF COST-SHARING INFORMATION.**

11 “(a) *PROVIDER DISCLOSURES.*—A provider that is in-
 12 network with respect to a group health plan or a health
 13 insurance issuer offering group or individual health insur-
 14 ance coverage shall provide to an enrollee in the plan or
 15 coverage who submits a request for the information de-
 16 scribed in paragraph (1) or (2), together with accurate and
 17 complete information about the enrollee’s coverage under the
 18 applicable plan or coverage—

19 “(1) as soon as practicable and not later than 2
 20 business days after the enrollee requests such informa-
 21 tion, a good faith estimate of the expected enrollee
 22 cost-sharing for the provision of a particular health
 23 care service (including any service that is reasonably
 24 expected to be provided in conjunction with such spe-
 25 cific service); and

1 “(2) as soon as practicable and not later than 2
 2 business days after an enrollee requests such informa-
 3 tion, the contact information for any ancillary pro-
 4 viders for a scheduled health care service.

5 “(b) *INSURER DISCLOSURES*.—A group health plan or
 6 a health insurance issuer offering group or individual
 7 health insurance coverage shall provide an enrollee in the
 8 plan or coverage with a good faith estimate of the enrollee’s
 9 cost-sharing (including deductibles, copayments, and coin-
 10 surance) for which the enrollee would be responsible for pay-
 11 ing with respect to a specific health care service (including
 12 any service that is reasonably expected to be provided in
 13 conjunction with such specific service), as soon as prac-
 14 ticable and not later than 2 business days after a request
 15 for such information by an enrollee.

16 “(c) *ENFORCEMENT*.—

17 “(1) *IN GENERAL*.—Subject to paragraph (2), a
 18 health care provider that violates a requirement under
 19 subsection (a) shall be subject to a civil monetary
 20 penalty of not more than \$10,000 for each act consti-
 21 tuting such violation.

22 “(2) *PROCEDURE*.—The provisions of section
 23 1128A of the Social Security Act, other than sub-
 24 sections (a) and (b) and the first sentence of sub-
 25 section (c)(1) of such section, shall apply to civil

1 *money penalties under this subsection in the same*
 2 *manner as such provisions apply to a penalty or pro-*
 3 *ceeding under section 1128A of the Social Security*
 4 *Act.”.*

5 *(b) EFFECTIVE DATE.—Section 2729G of the Public*
 6 *Health Service Act, as added by subsection (a), shall apply*
 7 *with respect to plan years beginning on or after the date*
 8 *that is 18 months after the date of enactment of this Act.*

9 **SEC. 310. STRENGTHENING PARITY IN MENTAL HEALTH**
 10 **AND SUBSTANCE USE DISORDER BENEFITS.**

11 *Section 2726 of the Public Health Service Act (42*
 12 *U.S.C. 300gg–26) is amended—*

13 *(1) in subsection (a), by adding at the end the*
 14 *following:*

15 “(8) **COMPLIANCE REQUIREMENTS.**—

16 “(A) **NONQUANTITATIVE TREATMENT LIMIT-**
 17 **TATION (NQTL) REQUIREMENTS.**—*In the case of a*
 18 *group health plan or a health insurance issuer*
 19 *offering group or individual health insurance*
 20 *coverage that provides both medical and surgical*
 21 *benefits and mental health or substance use dis-*
 22 *order benefits and that imposes nonquantitative*
 23 *treatment limitations (referred to in this section*
 24 *as ‘NQTL’) on mental health or substance use*
 25 *disorder benefits, the plan or issuer offering*

1 *health insurance coverage in connection with*
2 *such a plan, shall perform comparative analyses*
3 *of the design and application of NQTLs in ac-*
4 *cordance with the following process, and make*
5 *available to the applicable State authority (or,*
6 *as applicable, to the Secretary of Labor with re-*
7 *spect to group health plans or the Secretary of*
8 *Health and Human Services with respect to*
9 *health insurance coverage), upon request within*
10 *60 days beginning 6 months after the date of en-*
11 *actment of the Lower Health Care Costs Act, the*
12 *following information:*

13 *“(i) The specific plan or coverage*
14 *terms regarding the NQTL, that applies to*
15 *such plan or coverage, and a description of*
16 *all mental health or substance use disorder*
17 *and medical or surgical benefits to which it*
18 *applies in each respective benefits classifica-*
19 *tion.*

20 *“(ii) The factors used to determine that*
21 *the NQTL will apply to mental health or*
22 *substance use disorder benefits and medical*
23 *or surgical benefits.*

24 *“(iii) The evidentiary standards used*
25 *for the factors identified in clause (ii), when*

1 *applicable, provided that every factor shall*
2 *be defined and any other source or evidence*
3 *relied upon to design and apply the NQTL*
4 *to mental health or substance use disorder*
5 *benefits and medical or surgical benefits.*

6 “(iv) *The comparative analyses dem-*
7 *onstrating that the processes, strategies, evi-*
8 *dentiary standards, and other factors used*
9 *to design the NQTL, as written, and the op-*
10 *eration processes and strategies as written*
11 *and in operation that are used to apply the*
12 *NQTL for mental health or substance use*
13 *disorder benefits are comparable to, and are*
14 *applied no more stringently than, the proc-*
15 *esses, strategies, evidentiary standards, and*
16 *other factors used to design the NQTL, as*
17 *written, and the operation processes and*
18 *strategies as written and in operation that*
19 *are used to apply the NQTL to medical or*
20 *surgical benefits.*

21 “(v) *A disclosure of the specific find-*
22 *ings and conclusions reached by the plan or*
23 *coverage that the results of the analyses de-*
24 *scribed in this subparagraph indicate that*

1 *the plan or coverage is in compliance with*
 2 *this section.*

3 “(B) *SECRETARY REQUEST PROCESS.*—

4 “(i) *SUBMISSION UPON REQUEST.*—

5 *With respect to group health plans or health*
 6 *insurance coverage for which the Secretary*
 7 *is enforcing this section in accordance with*
 8 *section 2723, the Secretary, in consultation*
 9 *with the Secretary of Labor and the Sec-*
 10 *retary of Treasury, shall request that a*
 11 *group health plan or a health insurance*
 12 *issuer offering group or individual health*
 13 *insurance coverage submit the comparative*
 14 *analyses described in subparagraph (A) for*
 15 *plans that involve potential violations of*
 16 *this section concerning NQTLs and any*
 17 *other instances in which the Secretary de-*
 18 *termines appropriate. The Secretary shall*
 19 *request not fewer than 20 such analyses per*
 20 *year.*

21 “(ii) *ADDITIONAL INFORMATION.*—*In*
 22 *instances in which the Secretary has con-*
 23 *cluded that the plan or coverage has not*
 24 *submitted sufficient information for the Sec-*
 25 *retary to review the comparative analyses*

described in subparagraph (A), as requested under clause (i), the Secretary shall specify to the plan or coverage the information the plan or coverage must submit to be responsive to the request under clause (i) for the Secretary to review the comparative analyses described in subparagraph(A) for compliance with this section. Nothing in this paragraph shall require the Secretary to conclude that a plan is in compliance with this section solely based upon the inspection of the comparative analyses described in subparagraph (A), as requested under clause (i).

“(iii) *REQUIRED ACTION.*—In instances in which the Secretary has reviewed the comparative analyses described in subparagraph (A), as requested under clause (i), and determined that the plan or coverage is not in compliance with this section, the plan or coverage shall specify to the Secretary the actions the plan or coverage will take to be in compliance with this section. Documents or communications produced in connection with the Secretary’s rec-

1 *ommendations to the plan or coverage shall*
2 *not be subject to disclosure pursuant to sec-*
3 *tion 552 of title 5, United States Code.*

4 “(iv) *REPORT.*—Not later than 1 year
5 *after the date of enactment of this para-*
6 *graph, and annually thereafter, the Sec-*
7 *retary shall submit to the Committee on*
8 *Education and Labor of the House of Rep-*
9 *resentatives and the Committee on Health,*
10 *Education, Labor, and Pensions of the Sen-*
11 *ate a report that contains—*

12 “(I) *a summary of the compara-*
13 *tive analyses requested under clause*
14 *(i), except that the identity of each*
15 *plan or coverage and any contracted*
16 *entity of a plan or coverage shall be re-*
17 *dacted;*

18 “(II) *the Secretary’s conclusions*
19 *as to whether each plan or coverage*
20 *submitted sufficient information for the*
21 *Secretary to review the comparative*
22 *analyses requested under clause (i) for*
23 *compliance with this section;*

24 “(III) *for each plan or coverage*
25 *that did submit sufficient information*

1 *for the Secretary to review the com-*
 2 *parative analyses requested under*
 3 *clause (i), the Secretary's conclusions*
 4 *as to whether and why the plan or cov-*
 5 *erage is in compliance with the disclo-*
 6 *sure requirements under this section;*

7 “(IV) *the Secretary's specifica-*
 8 *tions described in clause (ii) for each*
 9 *plan or coverage that the Secretary de-*
 10 *termined did not submit sufficient in-*
 11 *formation for the Secretary to review*
 12 *the comparative analyses requested*
 13 *under clause (i) for compliance with*
 14 *this section; and*

15 “(V) *the Secretary's specifications*
 16 *described in clause (iii) of the actions*
 17 *each plan or coverage that the Sec-*
 18 *retary determined is not in compliance*
 19 *with this section must take to be in*
 20 *compliance with this section, including*
 21 *the reason why the Secretary deter-*
 22 *mined the plan or coverage is not in*
 23 *compliance.*

24 “(C) COMPLIANCE PROGRAM GUIDANCE

25 DOCUMENT UPDATE PROCESS.—

1 “(i) *IN GENERAL.*—*The Secretary shall*
 2 *include select instances of noncompliance*
 3 *that the Secretary discovers upon reviewing*
 4 *the comparative analyses requested under*
 5 *subparagraph (B)(i) in the compliance pro-*
 6 *gram guidance document described in sec-*
 7 *tion 2726(a)(6), as it is updated every 2*
 8 *years, except that all instances shall be*
 9 *deidentified and such instances shall not*
 10 *disclose any protected health information or*
 11 *individually identifiable information.*

12 “(ii) *GUIDANCE AND REGULATIONS.*—
 13 *Not later than 18 months after the date of*
 14 *enactment of this paragraph, the Secretary*
 15 *shall finalize any draft or interim guidance*
 16 *and regulations relating to mental health*
 17 *parity under this section.*

18 “(iii) *STATE.*—*The Secretary shall*
 19 *share information on findings of compliance*
 20 *and noncompliance discovered upon review-*
 21 *ing the comparative analyses requested*
 22 *under subparagraph (B)(i) shall be shared*
 23 *with the State where the group health plan*
 24 *is located or the State where the health in-*
 25 *surance issuer is licensed to do business for*

1 *coverage offered by a health insurance issuer*
 2 *in the group market, in accordance with*
 3 *section 2726(a)(6)(B)(iii)(II).”.*

4 **SEC. 311. TECHNICAL AMENDMENTS.**

5 (a) *ERISA*.—Section 715 of the *Employee Retirement*
 6 *Income Security Act of 1974* (29 U.S.C. 1185d) is amend-
 7 ed—

8 (1) in subsection (a)(1), by striking “(as amend-
 9 ed by the *Patient Protection and Affordable Care*
 10 *Act*)” and inserting “(including any subsequent
 11 amendments to such part)”; and

12 (2) in subsection (b)—

13 (A) by striking “(as amended by the *Patient*
 14 *Protection and Affordable Care Act*)” and insert-
 15 ing “(including any subsequent amendments to
 16 such part)”; and

17 (B) by striking “(as so amended)”.

18 (b) *IRC*.—Section 9815 of the *Internal Revenue Code*
 19 of 1986 is amended—

20 (1) in subsection (a)(1), by striking “(as amend-
 21 ed by the *Patient Protection and Affordable Care*
 22 *Act*)” and inserting “(including any subsequent
 23 amendments to such part)”; and

24 (2) in subsection (b)—

1 (A) by striking “(as amended by the Patient
2 Protection and Affordable Care Act)” and insert-
3 ing “(including any subsequent amendments to
4 such part)”; and

5 (B) by striking “(as so amended)”.

6 (c) *APPLICABILITY.*—The amendments made by sub-
7 sections (a) and (b) shall take effect as though included in
8 the enactment of the Patient Protection and Affordable Care
9 Act (Public Law 111–148).

10 **SEC. 312. THIRD-PARTY ADMINISTRATORS.**

11 Any obligation on a third-party administrator under
12 this Act (including the amendments made by this Act) shall
13 not affect any other direct or indirect requirement under
14 any other provision Federal law that applies to third-party
15 administrators offering services to group health plans.

16 **SEC. 313. GROUP HEALTH PLAN REPORTING REQUIRE-**
17 **MENTS.**

18 Part C of title XXVII of the Public Health Service Act
19 (42 U.S.C. 300gg–91 et seq.), as amended by section 303,
20 is further amended by adding at the end the following:

21 **“SEC. 2797. GROUP HEALTH PLAN REPORTING.**

22 “(a) *IN GENERAL.*—A group health plan or health in-
23 surance issuer offering group or individual health insur-
24 ance coverage shall submit to the Secretary, not later than

1 *March 1 of each year, the following information with re-*
 2 *spect to the health plan in the previous plan year:*

3 “(1) *The beginning and end dates of the plan*
 4 *year.*

5 “(2) *The number of enrollees.*

6 “(3) *Each State in which the plan is offered.*

7 “(4) *The 50 brand prescription drugs most fre-*
 8 *quently dispensed by pharmacies for claims paid by*
 9 *the issuer, and the total number of paid claims for*
 10 *each such drug.*

11 “(5) *The 50 most costly prescription drugs with*
 12 *respect to the plan by total annual spending, and the*
 13 *annual amount spent by the plan for each such drug.*

14 “(6) *The 50 prescription drugs with the greatest*
 15 *increase in plan expenditures over the plan year pre-*
 16 *ceding the plan year that is the subject of the report,*
 17 *and, for each such drug, the change in amounts ex-*
 18 *pended by the plan in each such plan year.*

19 “(7) *Total spending on health care services by*
 20 *such group health plan, broken down by—*

21 “(A) *the type of costs, including—*

22 “(i) *hospital costs;*

23 “(ii) *health care provider and clinical*
 24 *service costs;*

25 “(iii) *costs for prescription drugs; and*

1 “(iv) other medical costs; and

2 “(B) spending on prescription drugs by—

3 “(i) the health plan; and

4 “(ii) the enrollees.

5 “(8) The average monthly premium—

6 “(A) paid by employers on behalf of enroll-

7 ees; and

8 “(B) paid by enrollees.

9 “(9) Any impact on premiums by rebates, fees,

10 and any other remuneration paid by drug manufac-

11 turers to the plan or its administrators or service pro-

12 viders, with respect to prescription drugs prescribed

13 to enrollees in the plan, including—

14 “(A) the amounts so paid for each thera-

15 peutic class of drugs; and

16 “(B) the amounts so paid for each of the 25

17 drugs that yielded the highest amount of rebates

18 and other remuneration under the plan from

19 drug manufacturers during the plan year.

20 “(10) Any reduction in premiums and out-of-

21 pocket costs associated with rebates, fees, or other re-

22 muneration described in paragraph (9).

23 “(b) *REPORT*.—Not later than 18 months after the date

24 on which the first report is required under subsection (a)

25 and biannually thereafter, the Secretary, acting through the

1 *Assistant Secretary of Planning and Evaluation and in co-*
 2 *ordination with the Inspector General of the Department*
 3 *of Health and Human Services, shall make available on the*
 4 *internet website of the Department of Health and Human*
 5 *Services a report on prescription drug reimbursements*
 6 *under group health plans, prescription drug pricing trends,*
 7 *and the role of prescription drug costs in contributing to*
 8 *premium increases or decreases under such plans, aggre-*
 9 *gated in such a way as no drug or plan specific information*
 10 *will be made public.*

11 “(c) *PRIVACY PROTECTIONS.*—No confidential or trade
 12 *secret information submitted to the Secretary under sub-*
 13 *section (a) shall be included in the report under subsection*
 14 *(b).’’.*

15 **SEC. 314. STUDY BY COMPTROLLER GENERAL OF UNITED**
 16 **STATES.**

17 (a) *IN GENERAL.*—The Comptroller General of the
 18 *United States (referred to in this section as the “Comp-*
 19 *troller General”)* shall, in consultation with appropriate
 20 *stakeholders, conduct a study on the role of pharmacy ben-*
 21 *efit managers.*

22 (b) *PERMISSIBLE EXAMINATION.*—In conducting the
 23 *study required under subsection (a), the Comptroller Gen-*
 24 *eral may examine various qualitative and quantitative as-*

1 pects of the role of pharmacy benefit managers, such as the
 2 following:

3 (1) The role that pharmacy benefit managers
 4 play in the pharmaceutical supply chain.

5 (2) The state of competition among pharmacy
 6 benefit managers, including the market share for the
 7 Nation's largest pharmacy benefit managers.

8 (3) The use of rebates and fees by pharmacy ben-
 9 efit managers, including—

10 (A) the extent to which rebates are passed
 11 on to health plans and whether such rebates are
 12 passed on to individuals enrolled in such plans;

13 (B) the extent to which rebates are kept by
 14 such pharmacy benefit managers; and

15 (C) the role of any fees charged by such
 16 pharmacy benefit managers.

17 (4) Whether pharmacy benefit managers struc-
 18 ture their formularies in favor of high-rebate prescrip-
 19 tion drugs over lower-cost, lower-rebate alternatives.

20 (5) The average prior authorization approval
 21 time for pharmacy benefit managers.

22 (6) Factors affecting the use of step therapy by
 23 pharmacy benefit managers.

24 (c) *REPORT*.—Not later than 3 years after the date of
 25 enactment of this Act, the Comptroller General shall submit

1 *to the Secretary of Health and Human Services, the Com-*
 2 *mittee on Health, Education, Labor, and Pensions of the*
 3 *Senate, and the Committee on Energy and Commerce of*
 4 *the House of Representatives a report containing the results*
 5 *of the study conducted under subsection (a), including pol-*
 6 *icy recommendations.*

7 ***TITLE IV—IMPROVING PUBLIC***
 8 ***HEALTH***

9 ***SEC. 401. IMPROVING AWARENESS OF DISEASE PREVEN-***
 10 ***TION.***

11 *The Public Health Service Act is amended by striking*
 12 *section 313 of such Act (42 U.S.C. 245) and inserting the*
 13 *following:*

14 ***“SEC. 313. PUBLIC AWARENESS CAMPAIGN ON THE IMPOR-***
 15 ***TANCE OF VACCINATIONS.***

16 *“(a) IN GENERAL.—The Secretary, acting through the*
 17 *Director of the Centers for Disease Control and Prevention*
 18 *and in coordination with other offices and agencies, as ap-*
 19 *propriate, shall award competitive grants to one or more*
 20 *public or private entities to carry out a national, evidence-*
 21 *based campaign to increase awareness and knowledge of the*
 22 *safety and effectiveness of vaccines for the prevention and*
 23 *control of diseases, combat misinformation about vaccines,*
 24 *and disseminate scientific and evidence-based vaccine-re-*
 25 *lated information, with the goal of increasing rates of vac-*

1 *ination across all ages, as applicable, particularly in com-*
 2 *munities with low rates of vaccination, to reduce and elimi-*
 3 *nate vaccine-preventable diseases.*

4 “(b) *CONSULTATION.*—*In carrying out the campaign*
 5 *under this section, the Secretary shall consult with appro-*
 6 *priate public health and medical experts, including the Na-*
 7 *tional Academy of Medicine and medical and public health*
 8 *associations and nonprofit organizations, in the develop-*
 9 *ment, implementation, and evaluation of the evidence-based*
 10 *public awareness campaign.*

11 “(c) *REQUIREMENTS.*—*The campaign under this sec-*
 12 *tion shall—*

13 “(1) *be a national, evidence-based initiative;*

14 “(2) *include the development of resources for*
 15 *communities with low rates of vaccination, including*
 16 *culturally- and linguistically-appropriate resources,*
 17 *as applicable;*

18 “(3) *include the dissemination of vaccine infor-*
 19 *mation and communication resources to public health*
 20 *departments, health care providers, and health care*
 21 *facilities, including such providers and facilities that*
 22 *provide prenatal and pediatric care;*

23 “(4) *be complementary to, and coordinated with,*
 24 *any other Federal, State, local, or Tribal efforts, as*
 25 *appropriate; and*

1 “(5) assess the effectiveness of communication
2 strategies to increase rates of vaccination.

3 “(d) *ADDITIONAL ACTIVITIES.*—The campaign under
4 this section may—

5 “(1) include the use of television, radio, the
6 internet, and other media and telecommunications
7 technologies;

8 “(2) be focused to address specific needs of com-
9 munities and populations with low rates of vaccina-
10 tion; and

11 “(3) include the dissemination of scientific and
12 evidence-based vaccine-related information, such as—

13 “(A) advancements in evidence-based re-
14 search related to diseases that may be prevented
15 by vaccines and vaccine development;

16 “(B) information on vaccinations for indi-
17 viduals and communities, including individuals
18 for whom vaccines are not recommended by the
19 Advisory Committee for Immunization Practices,
20 and the effects of low vaccination rates within a
21 community on such individuals;

22 “(C) information on diseases that may be
23 prevented by vaccines; and

24 “(D) information on vaccine safety and the
25 systems in place to monitor vaccine safety.

1 “(e) *EVALUATION.*—*The Secretary shall—*

2 “(1) *establish benchmarks and metrics to quan-*
3 *titatively measure and evaluate the awareness cam-*
4 *paign under this section;*

5 “(2) *conduct qualitative assessments regarding*
6 *the awareness campaign under this section; and*

7 “(3) *prepare and submit to the Committee on*
8 *Health, Education, Labor, and Pensions of the Senate*
9 *and Committee on Energy and Commerce of the*
10 *House of Representatives an evaluation of the aware-*
11 *ness campaign under this section.*

12 “(f) *SUPPLEMENT NOT SUPPLANT.*—*Funds appro-*
13 *priated under this section shall be used to supplement and*
14 *not supplant other Federal, State, and local public funds*
15 *provided for activities described in this section.*

16 “(g) *AUTHORIZATION OF APPROPRIATIONS.*—*There*
17 *are authorized to be appropriated to carry out this section*
18 *and section 317(k) such sums as may be necessary for fiscal*
19 *years 2020 through 2024.”*

20 **SEC. 402. GRANTS TO ADDRESS VACCINE-PREVENTABLE**
21 **DISEASES.**

22 (a) *IN GENERAL.*—*Section 317(k)(1) of the Public*
23 *Health Service Act (42 U.S.C. 247b(k)(1)) is amended—*

24 (1) *in subparagraph (C), by striking “; and”*
25 *and inserting a semicolon;*

1 (2) in subparagraph (D), by striking the period
2 and inserting a semicolon; and

3 (3) by adding at the end the following:

4 “(E) planning, implementation, and evaluation
5 of activities to address vaccine-preventable diseases,
6 including activities to—

7 “(i) identify communities at high risk of
8 outbreaks related to vaccine-preventable diseases,
9 including through improved data collection and
10 analysis;

11 “(ii) pilot innovative approaches to improve
12 vaccination rates in communities and among
13 populations with low rates of vaccination;

14 “(iii) reduce barriers to accessing vaccines
15 and evidence-based information about the health
16 effects of vaccines;

17 “(iv) partner with community organiza-
18 tions and health care providers to develop and
19 deliver evidence-based interventions, including
20 culturally- and linguistically-appropriate inter-
21 ventions, to increase vaccination rates;

22 “(v) improve delivery of evidence-based vac-
23 cine-related information to parents and others;
24 and

1 “(vi) improve the ability of State, local,
2 tribal, and territorial public health departments
3 to engage communities at high risk for outbreaks
4 related to vaccine-preventable diseases; and

5 “(F) research related to strategies for improving
6 awareness of scientific and evidence-based vaccine-re-
7 lated information, including for communities with
8 low rates of vaccination, in order to understand bar-
9 riers to vaccination, improve vaccination rates, and
10 assess the public health outcomes of such strategies.”.

11 (b) *SUPPLEMENTAL GRANT FUNDS.*—Section
12 330(d)(1) of the Public Health Service Act (42 U.S.C. 254b)
13 is amended—

14 (1) in subparagraph (F), by striking “and” at
15 the end;

16 (2) in subparagraph (G), by striking the period
17 and and inserting “; and”; and

18 (3) by adding at the end the following:

19 “(H) improving access to recommended im-
20 munizations.”.

21 **SEC. 403. GUIDE ON EVIDENCE-BASED STRATEGIES FOR**
22 **PUBLIC HEALTH DEPARTMENT OBESITY PRE-**
23 **VENTION PROGRAMS.**

24 (a) *DEVELOPMENT AND DISSEMINATION OF AN EVI-*
25 *DENCE-BASED STRATEGIES GUIDE.*—The Secretary of

1 *Health and Human Services (referred to in this section as*
 2 *the “Secretary”), acting through the Director of the Centers*
 3 *for Disease Control and Prevention, not later than 2 years*
 4 *after the date of enactment of this Act, shall—*

5 (1) *develop a guide on evidence-based strategies*
 6 *for State, territorial, and local health departments to*
 7 *use to build and maintain effective obesity prevention*
 8 *and reduction programs, and, in consultation with*
 9 *Indian Tribes and Tribal organizations, a guide on*
 10 *such evidence-based strategies with respect to Indian*
 11 *Tribes and Tribal organizations for such Indian*
 12 *Tribes and Tribal organizations to use for such pur-*
 13 *pose, both of which guides shall—*

14 (A) *describe an integrated program struc-*
 15 *ture for implementing interventions proven to be*
 16 *effective in preventing and reducing the inci-*
 17 *dence of obesity; and*

18 (B) *recommend—*

19 (i) *optimal resources, including staff-*
 20 *ing and infrastructure, for promoting nutri-*
 21 *tion and obesity prevention and reduction;*
 22 *and*

23 (ii) *strategies for effective obesity pre-*
 24 *vention programs for State, territorial, and*
 25 *local health departments, Indian Tribes,*

1 *and Tribal organizations, including strate-*
2 *gies related to—*

3 *(I) the application of evidence-*
4 *based and evidence-informed practices*
5 *to prevent and reduce obesity rates;*

6 *(II) the development, implementa-*
7 *tion, and evaluation of obesity preven-*
8 *tion and reduction strategies for spe-*
9 *cific communities and populations;*

10 *(III) demonstrated knowledge of*
11 *obesity prevention practices that reduce*
12 *associated preventable diseases, health*
13 *conditions, death, and health care*
14 *costs;*

15 *(IV) best practices for the coordi-*
16 *nation of efforts to prevent and reduce*
17 *obesity and related chronic diseases;*

18 *(V) addressing the underlying risk*
19 *factors and social determinants of*
20 *health that impact obesity rates; and*

21 *(VI) interdisciplinary coordina-*
22 *tion between relevant public health of-*
23 *ficials specializing in fields such as*
24 *nutrition, physical activity, epidemi-*
25 *ology, communications, and policy im-*

1 *plementation, and collaboration be-*
 2 *tween public health officials, commu-*
 3 *nity-based organizations, and others,*
 4 *as appropriate; and*

5 *(2) disseminate the guides and current research,*
 6 *evidence-based practices, tools, and educational mate-*
 7 *rials related to obesity prevention, consistent with the*
 8 *guide, to State, territorial, and local health depart-*
 9 *ments, Indian Tribes, and Tribal organizations.*

10 *(b) TECHNICAL ASSISTANCE.—The Secretary, acting*
 11 *through the Director of the Centers for Disease Control and*
 12 *Prevention, shall provide technical assistance to State, ter-*
 13 *ritorial, and local health departments, Indian Tribes, and*
 14 *Tribal organizations to support such health departments in*
 15 *implementing the guide developed under subsection (a)(1).*

16 *(c) INDIAN TRIBES; TRIBAL ORGANIZATIONS.—The*
 17 *terms “Indian Tribe” and “Tribal organization” have the*
 18 *meanings given the terms “Indian tribe” and “tribal orga-*
 19 *nization”, respectively, in section 4 of the Indian Self-De-*
 20 *termination and Education Assistance Act (25 U.S.C.*
 21 *5304).*

22 **SEC. 404. EXPANDING CAPACITY FOR HEALTH OUTCOMES.**

23 *Title III of the Public Health Service Act is amended*
 24 *by inserting after section 330M (42 U.S.C. 254c–19) the*
 25 *following:*

1 **“SEC. 330N. EXPANDING CAPACITY FOR HEALTH OUT-**
 2 **COMES.**

3 “(a) *DEFINITIONS.—In this section:*

4 “(1) *ELIGIBLE ENTITY.—The term ‘eligible enti-*
 5 *ty’ means an entity providing health care services in*
 6 *rural areas, frontier areas, health professional short-*
 7 *age areas, or medically underserved areas, or to medi-*
 8 *cally underserved populations or Native Americans,*
 9 *including Indian tribes or tribal organizations.*

10 “(2) *HEALTH PROFESSIONAL SHORTAGE*
 11 *AREA.—The term ‘health professional shortage area’*
 12 *means a health professional shortage area designated*
 13 *under section 332.*

14 “(3) *INDIAN TRIBE.—The terms ‘Indian tribe’*
 15 *and ‘tribal organization’ have the meanings given*
 16 *such terms in section 4 of the Indian Self-Determina-*
 17 *tion and Education Assistance Act.*

18 “(4) *MEDICALLY UNDERSERVED POPULATION.—*
 19 *The term ‘medically underserved population’ has the*
 20 *meaning given the term in section 330(b)(3).*

21 “(5) *NATIVE AMERICANS.—The term ‘Native*
 22 *Americans’ has the meaning given such term in sec-*
 23 *tion 736 and includes Indian tribes and tribal orga-*
 24 *nizations.*

25 “(6) *TECHNOLOGY-ENABLED COLLABORATIVE*
 26 *LEARNING AND CAPACITY BUILDING MODEL.—The*

1 *term ‘technology-enabled collaborative learning and*
 2 *capacity building model’ means a distance health*
 3 *education model that connects health care profes-*
 4 *sionals, and particularly specialists, with multiple*
 5 *other health care professionals through simultaneous*
 6 *interactive videoconferencing for the purpose of facili-*
 7 *tating case-based learning, disseminating best prac-*
 8 *tices, and evaluating outcomes.*

9 *“(b) PROGRAM ESTABLISHED.—The Secretary shall,*
 10 *as appropriate, award grants to evaluate, develop, and, as*
 11 *appropriate, expand the use of technology-enabled collabo-*
 12 *rative learning and capacity building models, to increase*
 13 *access to health care services, such as those to address chron-*
 14 *ic diseases and conditions, mental health, substance use dis-*
 15 *orders, prenatal and maternal health, pediatric care, pain*
 16 *management, palliative care, and other specialty care in*
 17 *rural areas, frontier areas, health professional shortage*
 18 *areas, or medically underserved areas and for medically un-*
 19 *derserved populations or Native Americans, including In-*
 20 *dian Tribes and Tribal organizations.*

21 *“(c) USE OF FUNDS.—*

22 *“(1) IN GENERAL.—Grants awarded under sub-*
 23 *section (b) shall be used for—*

24 *“(A) the development and acquisition of in-*
 25 *structional programming, and the training of*

1 *health care providers and other professionals that*
2 *provide or assist in the provision of services*
3 *through such models;*

4 *“(B) information collection and evaluation*
5 *activities to study the impact of such models on*
6 *patient outcomes and health care providers, and*
7 *to identify best practices for the expansion and*
8 *use of such models; or*

9 *“(C) other activities consistent with achiev-*
10 *ing the objectives of the grants awarded under*
11 *this section, as determined by the Secretary.*

12 *“(2) OTHER USES.—In addition to any of the*
13 *uses under paragraph (1), grants awarded under sub-*
14 *section (b) may be used for—*

15 *“(A) equipment to support the use and ex-*
16 *pansion of technology-enabled collaborative*
17 *learning and capacity building models, includ-*
18 *ing for hardware and software that enables dis-*
19 *tance learning, health care provider support, and*
20 *the secure exchange of electronic health informa-*
21 *tion; or*

22 *“(B) support for health care providers and*
23 *other professionals that provide or assist in the*
24 *provision of services through such models.*

1 “(d) *LENGTH OF GRANTS.*—Grants awarded under
2 subsection (b) shall be for a period of up to 5 years.

3 “(e) *APPLICATION.*—An eligible entity that seeks to re-
4 ceive a grant under subsection (b) shall submit to the Sec-
5 retary an application, at such time, in such manner, and
6 containing such information as the Secretary may require.
7 Such application criteria shall include an assessment of the
8 effect of technology-enabled collaborative learning and ca-
9 pacity building models on patient outcomes and health care
10 providers.

11 “(f) *ACCESS TO BROADBAND.*—In administering
12 grants under this section, the Secretary may coordinate
13 with other agencies to ensure that funding opportunities are
14 available to support access to reliable, high-speed internet
15 for grantees.

16 “(g) *TECHNICAL ASSISTANCE.*—The Secretary shall
17 provide (either directly through the Department of Health
18 and Human Services or by contract) technical assistance
19 to eligible entities, including recipients of grants under sub-
20 section (b), on the development, use, and evaluation of tech-
21 nology-enabled collaborative learning and capacity building
22 models in order to expand access to health care services pro-
23 vided by such entities, including for medically underserved
24 areas and to medically underserved populations or Native

1 *Americans, including Indian tribes and Tribal organiza-*
 2 *tions.*

3 “(h) *RESEARCH AND EVALUATION.*—*The Secretary, in*
 4 *consultation with stakeholders with appropriate expertise*
 5 *in such models, shall develop a strategic plan to research*
 6 *and evaluate the evidence for such models. The Secretary*
 7 *shall use such plan to inform the activities carried out*
 8 *under this section.*

9 “(i) *REPORT BY SECRETARY.*—*Not later than 4 years*
 10 *after the date of enactment of this section, the Secretary*
 11 *shall prepare and submit to the Committee on Health, Edu-*
 12 *cation, Labor, and Pensions of the Senate and the Com-*
 13 *mittee on Energy and Commerce of the House of Represent-*
 14 *atives, and post on the Internet website of the Department*
 15 *of Health and Human Services, a report including, at min-*
 16 *imum—*

17 “(1) *a description of any new and continuing*
 18 *grants awarded to entities under subsection (b) and*
 19 *the specific purpose and amounts of such grants;*

20 “(2) *an overview of—*

21 “(A) *the evaluations conducted under sub-*
 22 *sections (b) or (f); and*

23 “(B) *technical assistance provided under*
 24 *subsection (g); and*

1 “(3) a description of any significant findings or
 2 developments in patient outcomes and health care
 3 providers and best practices for eligible entities ex-
 4 panding, using, or evaluating technology-enabled col-
 5 laborative learning and capacity building models, in-
 6 cluding through the activities described in subsection
 7 (g).

8 “(j) *AUTHORIZATION OF APPROPRIATIONS.*—There is
 9 authorized to be appropriated to carry out this section, such
 10 sums as may be necessary for each of fiscal years 2020
 11 through 2024.”.

12 **SEC. 405. PUBLIC HEALTH DATA SYSTEM MODERNIZATION.**

13 *Subtitle C of title XXVIII of the Public Health Service*
 14 *Act (42 U.S.C. 300hh–31 et seq.) is amended by adding at*
 15 *the end the following:*

16 **“SEC. 2822. PUBLIC HEALTH DATA SYSTEM MODERNIZA-**
 17 **TION GRANTS.**

18 “(a) *IN GENERAL.*—The Secretary, acting through the
 19 Director of the Centers for Disease Control and Prevention,
 20 shall—

21 “(1) award grants to State, local, Tribal, and
 22 territorial public health departments for the expan-
 23 sion and modernization of public health data systems,
 24 to assist public health departments in—

1 “(A) assessing current data infrastructure
2 capabilities and gaps to improve and increase
3 consistency in data collection, storage, analysis,
4 and, as appropriate, to improve dissemination of
5 public health-related information;

6 “(B) improving secure public health data
7 collection, transmission, exchange, maintenance,
8 and analysis;

9 “(C) simplifying and supporting reporting
10 by health care providers, as applicable, pursuant
11 to State law, including through the use of health
12 information technology, to State, local, Tribal,
13 and territorial public health departments, in-
14 cluding public health officials in multiple juris-
15 dictions within such State, as appropriate;

16 “(D) enhancing interoperability of public
17 health data systems (including systems created
18 or accessed by public health departments) with
19 health information technology, including health
20 information technology certified under section
21 3001(c)(5);

22 “(E) supporting earlier disease and health
23 condition detection, such as through near real-
24 time data monitoring, to support rapid public
25 health responses; and

1 “(F) supporting activities within the appli-
 2 cable jurisdiction related to the expansion and
 3 modernization of electronic case reporting;

4 “(2) as appropriate, conduct activities related to
 5 the interoperability and improvement of applicable
 6 public health data systems used by the Centers for
 7 Disease Control and Prevention, and, in coordination
 8 with the Office of the National Coordinator for Health
 9 Information Technology, the designation of data and
 10 technology standards for health information systems
 11 of the public health infrastructure with deference
 12 given to standards published by standards develop-
 13 ment organizations and voluntary consensus-based
 14 standards bodies; and

15 “(3) develop and utilize public-private partner-
 16 ships for technical assistance and related implementa-
 17 tion support for State, local, Tribal, and territorial
 18 public health departments, and the Centers for Dis-
 19 ease Control and Prevention, on the expansion and
 20 modernization of electronic case reporting and public
 21 health data systems, as applicable.

22 “(b) REQUIREMENTS.—

23 “(1) IN GENERAL.—The Secretary may not
 24 award a grant under subsection (a)(1) unless the ap-
 25 plicant uses or agrees to use standards recognized by

1 *the National Coordinator for Health Information*
 2 *Technology pursuant to section 3001(c)(1) or adopted*
 3 *by the Secretary under section 3004.*

4 “(2) *WAIVER.—The Secretary may waive the re-*
 5 *quirement under paragraph (1) with respect to an*
 6 *applicant if the Secretary determines that the activi-*
 7 *ties under subsection (a) cannot otherwise be carried*
 8 *out within the applicable jurisdiction.*

9 “(3) *APPLICATION.—A State, local, Tribal, or*
 10 *territorial health department applying for a grant*
 11 *under this section shall submit an application to the*
 12 *Secretary at such time and in such manner as the*
 13 *Secretary may require. Such application shall include*
 14 *information describing—*

15 “(A) *the activities that will be supported by*
 16 *the grant; and*

17 “(B) *how the modernization of such public*
 18 *health data systems will support or impact the*
 19 *public health infrastructure of the health depart-*
 20 *ment, including a description of remaining gaps,*
 21 *if any, and the actions needed to address such*
 22 *gaps.*

23 “(c) *USE OF FUNDS.—An entity receiving a grant*
 24 *under this section may use amounts received under such*
 25 *grant for one or both of the following:*

1 “(1) *Carrying out activities described in sub-*
 2 *section (a)(1) to support public health data systems*
 3 *(including electronic case reporting), which may in-*
 4 *clude support for, and training of, professionals with*
 5 *expertise in contributing to and using such systems*
 6 *(including public health data scientists).*

7 “(2) *Developing and disseminating information*
 8 *related to the use and importance of public health*
 9 *data.*

10 “(d) *STRATEGY AND IMPLEMENTATION PLAN.—Not*
 11 *later than 180 days after the date of enactment of the Lower*
 12 *Health Care Costs Act, the Secretary, acting through the*
 13 *Director of the Centers for Disease Control and Prevention,*
 14 *shall submit to the Committee on Health, Education, Labor,*
 15 *and Pensions of the Senate and the Committee on Energy*
 16 *and Commerce of the House of Representatives, a coordi-*
 17 *nated strategy and an accompanying implementation plan*
 18 *that identifies and demonstrates the steps the Secretary will*
 19 *carry out to—*

20 “(1) *update and improve applicable public*
 21 *health data systems used by the Centers for Disease*
 22 *Control and Prevention; and*

23 “(2) *carry out the activities described in this sec-*
 24 *tion to support the improvement of State, local, Trib-*
 25 *al, and territorial public health data systems.*

1 “(e) *CONSULTATION.*—*The Secretary, acting through*
 2 *the Director of the Centers for Disease Control and Preven-*
 3 *tion, shall consult with State, local, Tribal, and territorial*
 4 *health departments, professional medical and public health*
 5 *associations, associations representing hospitals or other*
 6 *health care entities, health information technology experts,*
 7 *and other appropriate entities regarding the plan and*
 8 *grant program to modernize public health data systems*
 9 *pursuant to this section. Such activities may include the*
 10 *provision of technical assistance related to the exchange of*
 11 *information by such public health data systems used by rel-*
 12 *evant health care and public health entities at the local,*
 13 *State, Federal, Tribal, and territorial levels.*

14 “(f) *REPORT TO CONGRESS.*—*Not later than 1 year*
 15 *after the date of enactment of this section, the Secretary*
 16 *shall submit a report to the Committee on Health, Edu-*
 17 *cation, Labor, and Pensions of the Senate and the Com-*
 18 *mittee on Energy and Commerce of the House of Represent-*
 19 *atives that includes—*

20 “(1) *a description of any barriers to—*

21 “(A) *public health authorities implementing*
 22 *interoperable public health data systems and*
 23 *electronic case reporting;*

24 “(B) *the exchange of information pursuant*
 25 *to electronic case reporting; or*

1 “(C) reporting by health care providers
 2 using such public health data systems, as appro-
 3 priate, and pursuant to State law;

4 “(2) an assessment of the potential public health
 5 impact of implementing electronic case reporting and
 6 interoperable public health data systems; and

7 “(3) a description of the activities carried out
 8 pursuant to this section.

9 “(g) *ELECTRONIC CASE REPORTING.*—In this section,
 10 the term ‘electronic case reporting’ means the automated
 11 identification, generation, and bilateral exchange of reports
 12 of health events among electronic health record or health
 13 information technology systems and public health authori-
 14 ties.

15 “(h) *AUTHORIZATION OF APPROPRIATIONS.*—For the
 16 purpose of carrying out this section, there are authorized
 17 to be appropriated such sums as may be necessary for fiscal
 18 years 2020 through 2024.”.

19 **SEC. 406. INNOVATION FOR MATERNAL HEALTH.**

20 Title III of the Public Health Service Act is amended
 21 by inserting after section 330N of such Act, as added by
 22 section 404, the following:

23 **“SEC. 330O. INNOVATION FOR MATERNAL HEALTH.**

24 “(a) *IN GENERAL.*—The Secretary, in consultation
 25 with experts representing a variety of clinical specialties,

1 *State, tribal, or local public health officials, researchers,*
 2 *epidemiologists, statisticians, and community organiza-*
 3 *tions, shall establish or continue a program to award com-*
 4 *petitive grants to eligible entities for the purpose of—*

5 “(1) *identifying, developing, or disseminating*
 6 *best practices to improve maternal health care quality*
 7 *and outcomes, eliminate preventable maternal mor-*
 8 *tality and severe maternal morbidity, and improve*
 9 *infant health outcomes, which may include—*

10 “(A) *information on evidence-based prac-*
 11 *tices to improve the quality and safety of mater-*
 12 *nal health care in hospitals and other health care*
 13 *settings of a State or health care system, includ-*
 14 *ing by addressing topics commonly associated*
 15 *with health complications or risks related to pre-*
 16 *natal care, labor care, birthing, and postpartum*
 17 *care;*

18 “(B) *best practices for improving maternal*
 19 *health care based on data findings and reviews*
 20 *conducted by a State maternal mortality review*
 21 *committee that address topics of relevance to*
 22 *common complications or health risks related to*
 23 *prenatal care, labor care, birthing, and*
 24 *postpartum care; and*

1 “(C) information on addressing deter-
 2 minants of health that impact maternal health
 3 outcomes for women before, during, and after
 4 pregnancy;

5 “(2) collaborating with State maternal mortality
 6 review committees to identify issues for the develop-
 7 ment and implementation of evidence-based practices
 8 to improve maternal health outcomes and reduce pre-
 9 ventable maternal mortality and severe maternal
 10 morbidity;

11 “(3) providing technical assistance and sup-
 12 porting the implementation of best practices identi-
 13 fied in paragraph (1) to entities providing health
 14 care services to pregnant and postpartum women; and

15 “(4) identifying, developing, and evaluating new
 16 models of care that improve maternal and infant
 17 health outcomes, which may include the integration of
 18 community-based services and clinical care.

19 “(b) *ELIGIBLE ENTITIES*.—To be eligible for a grant
 20 under subsection (a), an entity shall—

21 “(1) submit to the Secretary an application at
 22 such time, in such manner, and containing such in-
 23 formation as the Secretary may require; and

24 “(2) demonstrate in such application that the
 25 entity is capable of carrying out data-driven mater-

1 *nal safety and quality improvement initiatives in the*
 2 *areas of obstetrics and gynecology or maternal health.*

3 *“(c) AUTHORIZATION OF APPROPRIATIONS.—To carry*
 4 *out this section, there is authorized to be appropriated such*
 5 *sums as may be necessary for each of fiscal years 2020*
 6 *through 2024.”.*

7 **SEC. 407. TRAINING FOR HEALTH CARE PROVIDERS.**

8 *Title VII of the Public Health Service Act is amended*
 9 *by striking section 763 (42 U.S.C. 294p) and inserting the*
 10 *following:*

11 **“SEC. 763. TRAINING FOR HEALTH CARE PROVIDERS.**

12 *“(a) GRANT PROGRAM.—The Secretary shall establish*
 13 *a program to award grants to accredited schools of*
 14 *allopathic medicine, osteopathic medicine, and nursing,*
 15 *and other health professional training programs for the*
 16 *training of health care professionals to reduce and prevent*
 17 *discrimination (including training related to implicit bi-*
 18 *ases) in the provision of health care services related to pre-*
 19 *natal care, labor care, birthing, and postpartum care.*

20 *“(b) ELIGIBILITY.—To be eligible for a grant under*
 21 *subsection (a), an entity described in such subsection shall*
 22 *submit to the Secretary an application at such time, in*
 23 *such manner, and containing such information as the Sec-*
 24 *retary may require.*

1 “(c) *REPORTING REQUIREMENT.*—*Each entity award-*
 2 *ed a grant under this section shall periodically submit to*
 3 *the Secretary a report on the status of activities conducted*
 4 *using the grant, including a description of the impact of*
 5 *such training on patient outcomes, as applicable.*

6 “(d) *BEST PRACTICES.*—*The Secretary may identify*
 7 *and disseminate best practices for the training of health*
 8 *care professionals to reduce and prevent discrimination (in-*
 9 *cluding training related to implicit biases) in the provision*
 10 *of health care services related to prenatal care, labor care,*
 11 *birthing, and postpartum care.*

12 “(e) *AUTHORIZATION OF APPROPRIATIONS.*—*To carry*
 13 *out this section, there is authorized to be appropriated such*
 14 *sums as may be necessary for each of fiscal years 2020*
 15 *through 2024.”.*

16 **SEC. 408. STUDY ON TRAINING TO REDUCE AND PREVENT**
 17 **DISCRIMINATION.**

18 *Not later than 2 years after date of enactment of this*
 19 *Act, the Secretary of Health and Human Services (referred*
 20 *to in this section as the “Secretary”) shall, through a con-*
 21 *tract with an independent research organization, conduct*
 22 *a study and make recommendations for accredited schools*
 23 *of allopathic medicine, osteopathic medicine, and nursing,*
 24 *and other health professional training programs on best*
 25 *practices related to training to reduce and prevent dis-*

1 *crimination, including training related to implicit biases,*
 2 *in the provision of health care services related to prenatal*
 3 *care, labor care, birthing, and postpartum care.*

4 **SEC. 409. PERINATAL QUALITY COLLABORATIVES.**

5 *Section 317K(a)(2) of the Public Health Service Act*
 6 *(42 U.S.C. 247b–12(a)(2)) is amended by adding at the end*
 7 *the following:*

8 *“(E)(i) The Secretary, acting through the*
 9 *Director of the Centers for Disease Control and*
 10 *Prevention and in coordination with other offices*
 11 *and agencies, as appropriate, shall establish or*
 12 *continue a competitive grant program for the es-*
 13 *tablishment or support of perinatal quality*
 14 *collaboratives to improve perinatal care and*
 15 *perinatal health outcomes for pregnant and*
 16 *postpartum women and their infants. A State,*
 17 *Indian Tribe, or Tribal organization may use*
 18 *funds received through such grant to—*

19 *“(I) support the use of evidence-based*
 20 *or evidence-informed practices to improve*
 21 *outcomes for maternal and infant health;*

22 *“(II) work with clinical teams; experts;*
 23 *State, local, and, as appropriate, tribal*
 24 *public health officials; and stakeholders, in-*
 25 *cluding patients and families, to identify,*

1 develop, or disseminate best practices to im-
 2 prove perinatal care and outcomes; and

3 “(III) employ strategies that provide
 4 opportunities for health care professionals
 5 and clinical teams to collaborate across
 6 health care settings and disciplines, includ-
 7 ing primary care and mental health, as ap-
 8 propriate, to improve maternal and infant
 9 health outcomes, which may include the use
 10 of data to provide timely feedback across
 11 hospital and clinical teams to inform re-
 12 sponses, and to provide support and train-
 13 ing to hospital and clinical teams for qual-
 14 ity improvement, as appropriate.

15 “(ii) To be eligible for a grant under clause
 16 (i), an entity shall submit to the Secretary an
 17 application in such form and manner and con-
 18 taining such information as the Secretary may
 19 require.”.

20 **SEC. 410. INTEGRATED SERVICES FOR PREGNANT AND**
 21 **POSTPARTUM WOMEN.**

22 (a) *GRANTS.*—Title III of the Public Health Service
 23 Act is amended by inserting after section 330O of such Act,
 24 as added by section 406, the following:

1 **“SEC. 330P. INTEGRATED SERVICES FOR PREGNANT AND**
 2 **POSTPARTUM WOMEN.**

3 “(a) *IN GENERAL.*—*The Secretary may award grants*
 4 *for the purpose of establishing or operating evidence-based*
 5 *or innovative, evidence-informed programs to deliver inte-*
 6 *grated health care services to pregnant and postpartum*
 7 *women to optimize the health of women and their infants,*
 8 *including to reduce adverse maternal health outcomes, preg-*
 9 *nancy-related deaths, and related health disparities (includ-*
 10 *ing such disparities associated with racial and ethnic mi-*
 11 *nority populations), and, as appropriate, by addressing*
 12 *issues researched under subsection (b)(2) of section 317K.*

13 “(b) *INTEGRATED SERVICES FOR PREGNANT AND*
 14 *POSTPARTUM WOMEN.*—

15 “(1) *ELIGIBILITY.*—*To be eligible to receive a*
 16 *grant under subsection (a), a State, Indian Tribe, or*
 17 *Tribal organization (as such terms are defined in sec-*
 18 *tion 4 of the Indian Self-Determination and Edu-*
 19 *cation Assistance Act) shall work with relevant stake-*
 20 *holders that coordinate care (including coordinating*
 21 *resources and referrals for health care and social serv-*
 22 *ices) to develop and carry out the program, includ-*
 23 *ing—*

24 “(A) *State, Tribal, and local agencies re-*
 25 *sponsible for Medicaid, public health, social serv-*

ices, mental health, and substance use disorder treatment and services;

“(B) health care providers who serve pregnant and postpartum women; and

“(C) community-based health organizations and health workers, including providers of home visiting services and individuals representing communities with disproportionately high rates of maternal mortality and severe maternal morbidity, and including those representing racial and ethnicity minority populations.

“(2) *TERMS.*—

“(A) *PERIOD.*—A grant awarded under subsection (a) shall be made for a period of 5 years. Any supplemental award made to a grantee under subsection (a) may be made for a period of less than 5 years.

“(B) *PREFERENCE.*—In awarding grants under subsection (a), the Secretary shall—

“(i) give preference to States, Indian Tribes, and Tribal organizations that have the highest rates of maternal mortality and severe maternal morbidity relative to other such States, Indian Tribes, or Tribal organizations, respectively; and

1 “(ii) shall consider health disparities
 2 related to maternal mortality and severe
 3 maternal morbidity, including such dispari-
 4 ties associated with racial and ethnic mi-
 5 nority populations.

6 “(C) *PRIORITY*.—In awarding grants under
 7 subsection (a), the Secretary shall give priority
 8 to applications from up to 15 entities described
 9 in subparagraph (B)(i).

10 “(D) *EVALUATION*.—The Secretary shall re-
 11 quire grantees to evaluate the outcomes of the
 12 programs supported under the grant.

13 “(c) *AUTHORIZATION OF APPROPRIATIONS*.—There are
 14 authorized to be appropriated to carry out this section such
 15 sums as may be necessary for each of fiscal years 2020
 16 through 2024.”.

17 (b) *REPORT ON GRANT OUTCOMES AND DISSEMINA-*
 18 *TION OF BEST PRACTICES*.—

19 (1) *REPORT*.—Not later than February 1, 2026,
 20 the Secretary of Health and Human Services shall
 21 submit to the Committee on Health, Education,
 22 Labor, and Pensions of the Senate and the Committee
 23 on Energy and Commerce of the House of Representa-
 24 tives a report that describes—

1 (A) the outcomes of the activities supported
2 by the grants awarded under the amendments
3 made by this section on maternal and child
4 health;

5 (B) best practices and models of care used
6 by recipients of grants under such amendments;
7 and

8 (C) obstacles identified by recipients of
9 grants under such amendments, and strategies
10 used by such recipients to deliver care, improve
11 maternal and child health, and reduce health
12 disparities.

13 (2) *DISSEMINATION OF BEST PRACTICES.*—Not
14 later than August 1, 2026, the Secretary of Health
15 and Human Services shall disseminate information
16 on best practices and models of care used by recipi-
17 ents of grants under the amendments made by this
18 section (including best practices and models of care
19 relating to the reduction of health disparities, includ-
20 ing such disparities associated with racial and ethnic
21 minority populations, in rates of maternal mortality
22 and severe maternal morbidity) to relevant stake-
23 holders, which may include health providers, medical
24 schools, nursing schools, relevant State, tribal, and
25 local agencies, and the general public.

1 **SEC. 411. EXTENSION FOR COMMUNITY HEALTH CENTERS,**
 2 **THE NATIONAL HEALTH SERVICE CORPS, AND**
 3 **TEACHING HEALTH CENTERS THAT OPERATE**
 4 **GME PROGRAMS.**

5 (a) *COMMUNITY HEALTH CENTERS.*—Section
 6 10503(b)(1)(F) of the Patient Protection and Affordable
 7 Care Act (42 U.S.C. 254b–2(b)(1)(F)) is amended by strik-
 8 ing “fiscal year 2019” and inserting “each of fiscal years
 9 2019 through 2024”.

10 (b) *NATIONAL HEALTH SERVICE CORPS.*—Section
 11 10503(b)(2)(F) of the Patient Protection and Affordable
 12 Care Act (42 U.S.C. 254b–2(b)(2)(F)) is amended by strik-
 13 ing “and 2019” and inserting “through 2024”.

14 (c) *TEACHING HEALTH CENTERS THAT OPERATE*
 15 *GRADUATE MEDICAL EDUCATION PROGRAMS.*—Section
 16 340H(g)(1) of the Public Health Service Act (42 U.S.C.
 17 256h(g)(1)) is amended by striking “and 2019” and insert-
 18 ing “through 2024”.

19 (d) *APPLICATION OF PROVISIONS.*—Amounts appro-
 20 priated pursuant to this section for each of fiscal years 2019
 21 through 2024 shall be subject to the requirements contained
 22 in Public Law 115–245 for funds for programs authorized
 23 under sections 330 through 340 of the Public Health Service
 24 Act.

25 (e) *CONFORMING AMENDMENTS.*—Paragraph (4) of
 26 section 3014(h) of title 18, United States Code, as amended

1 *by section 50901 of Public Law 115–123, is amended by*
 2 *striking “and section 50901(e) of the Advancing Chronic*
 3 *Care, Extenders, and Social Services Act” and inserting “,*
 4 *section 50901(e) of the Advancing Chronic Care, Extenders,*
 5 *and Social Services Act, and section 411(d) of the Lower*
 6 *Health Care Costs Act”.*

7 **SEC. 412. OTHER PROGRAMS.**

8 (a) *TYPE I.*—Section 330B(b)(2)(D) of the Public
 9 *Health Service Act (42 U.S.C. 254c–2(b)(2)(D)) is amended*
 10 *by striking “and 2019” and inserting “through 2024”.*

11 (b) *INDIANS.*—Subparagraph (D) of section 330C(c)(2)
 12 *of the Public Health Service Act (42 U.S.C. 254c–*
 13 *3(c)(2)(D)) is amended by striking “and 2019” and insert-*
 14 *ing “through 2024”.*

15 **SEC. 413. NATIVE AMERICAN SUICIDE PREVENTION.**

16 Section 520E(b) of the Public Health Service Act (42
 17 *U.S.C. 290bb–36(b) is amended by inserting after para-*
 18 *graph (3) the following:*

19 “(4) *CONSULTATION.*—A State applying for a
 20 *grant or cooperative agreement under this section*
 21 *shall, in the development and implementation of a*
 22 *statewide early intervention strategy, consult or con-*
 23 *fer with entities described in paragraph (1)(C) in*
 24 *such State.”.*

1 **SEC. 414. MINIMUM AGE OF SALE OF TOBACCO PRODUCTS.**

2 (a) *IN GENERAL.*—Section 906(d) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 387f(d)) is amended—

4 (1) in paragraph (3)(A)(ii), by striking “18
5 years” and inserting “21 years”; and

6 (2) by adding at the end the following:

7 “(5) *MINIMUM AGE OF SALE.*—It shall be unlaw-
8 ful for any retailer to sell a tobacco product to any
9 person younger than 21 years of age.”.

10 (b) *REGULATIONS.*—Not later than 180 days after the
11 date of enactment of this Act, the Secretary of Health and
12 Human Services (referred to in this section as the “Sec-
13 retary”) shall publish in the Federal Register a final rule
14 to update the regulations issued under chapter IX of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387 et
16 seq.) as appropriate, only to carry out the amendments
17 made by subsection (a), including updating the relevant age
18 verification requirements under part 1140 of title 21, Code
19 of Federal Regulations to require age verification for indi-
20 viduals under the age of 30. Such final rule shall—

21 (1) take full effect not later than 90 days after
22 the date on which such final rule is published; and

23 (2) be deemed to be in compliance with all appli-
24 cable provisions of chapter 5 of title 5, United States
25 Code and all other provisions of law relating to rule-
26 making procedures.

1 (c) *NOTIFICATION.*—Not later than 90 days after the
 2 date of enactment of this Act, the Secretary shall provide
 3 written notification to the Committee on Health, Edu-
 4 cation, Labor, and Pensions of the Senate and the Com-
 5 mittee on Energy and Commerce of the House of Represent-
 6 atives regarding the progress of the Department of Health
 7 and Human Services towards promulgating the final rule
 8 under subsection (b). If, 180 days after the date of enact-
 9 ment of this Act, such rule has not been promulgated in
 10 accordance with subsection (b), the Secretary shall provide
 11 a written notification and a justification for the delay in
 12 rulemaking to such committees.

13 (d) *PENALTIES FOR VIOLATIONS.*—

14 (1) *IN GENERAL.*—Section 103(q)(2) of the Fam-
 15 ily Smoking Prevention and Tobacco Control Act
 16 (Public Law 111–31) is amended—

17 (A) in subparagraph (A), in the matter pre-
 18 ceding clause (i), by inserting “section 906(d)(5)
 19 or of” after “violations of”; and

20 (B) in subparagraph (C), by inserting “sec-
 21 tion 906(d)(5) or of” after “a retailer of”.

22 (2) *REPEATED VIOLATIONS.*—Section 303(f)(8)
 23 of the Federal Food, Drug, and Cosmetic Act (21
 24 U.S.C. 333(f)(8)) is amended by inserting “section
 25 906(d)(5) or of” after “repeated violations of”.

1 (3) *MISBRANDED PRODUCTS.—Section*
 2 *903(a)(7)(B) of the Federal Food, Drug, and Cosmetic*
 3 *Act (21 U.S.C. 387c) is amended by inserting “sec-*
 4 *tion 906(d)(5) or of” after “violation of”.*

5 **SEC. 415. SALE OF TOBACCO PRODUCTS TO INDIVIDUALS**
 6 **UNDER THE AGE OF 21.**

7 (a) *IN GENERAL.—Section 1926 of the Public Health*
 8 *Service Act (42 U.S.C. 300x–26) is amended—*

9 (1) *in the heading—*

10 (A) *by striking “STATE LAW REGARD-*
 11 *ING”; and*

12 (B) *by striking “18” and inserting “21”;*

13 (2) *by striking subsections (a) and (d);*

14 (3) *by redesignating subsections (b) and (c) as*
 15 *subsections (a) and (b), respectively;*

16 (4) *by amending subsection (a), as so redesign-*
 17 *ated, to read as follows:*

18 “(a) *IN GENERAL.—A funding agreement for a grant*
 19 *under section 1921 is that the State involved will—*

20 “(1) *annually conduct random, unannounced in-*
 21 *spections to ensure that retailers do not sell tobacco*
 22 *products to individuals under the age of 21; and*

23 “(2) *annually submit to the Secretary a report*
 24 *describing—*

1 “(A) the activities carried out by the State
2 to ensure that retailers do not sell tobacco prod-
3 ucts to individuals under the age of 21;

4 “(B) the extent of success the State has
5 achieved in ensuring that retailers do not sell to-
6 bacco products to individuals under the age of
7 21; and

8 “(C) the strategies to be utilized by the
9 State to ensure that retailers do not sell tobacco
10 products to individuals under the age of 21 dur-
11 ing the fiscal year for which the grant is
12 sought.”;

13 (5) in subsection (b), as so redesignated—

14 (A) by striking paragraphs (1), (2), (3),
15 and (4);

16 (B) by striking “Before making” and in-
17 serting the following:

18 “(1) IN GENERAL.—Before making”;

19 (C) by striking “for the first applicable fis-
20 cal year or any subsequent fiscal year”;

21 (D) by striking “subsections (a) and (b)”
22 and inserting “subsection (a)”;

23 (E) by striking “equal to—” and inserting
24 “up to 10 percent of the amount determined

1 *under section 1933 for the State for the applica-*
 2 *ble fiscal year.”; and*

3 *(F) by adding at the end the following:*

4 “(2) *LIMITATION.—*

5 “(A) *IN GENERAL.—A State shall not have*
 6 *funds withheld pursuant to paragraph (1) if*
 7 *such State for which the Secretary has made a*
 8 *determination of noncompliance under such*
 9 *paragraph—*

10 “(i) *certifies to the Secretary by May*
 11 *1 of the fiscal year for which the funds are*
 12 *appropriated, consistent with subparagraph*
 13 *(B), that the State will commit additional*
 14 *State funds, in accordance with paragraph*
 15 *(1), to ensure that retailers do not sell to-*
 16 *bacco products to individuals under 21*
 17 *years of age;*

18 “(ii) *agrees to comply with a nego-*
 19 *tiated agreement for a corrective action*
 20 *plan that is approved by the Secretary and*
 21 *carried out in accordance with guidelines*
 22 *issued by the Secretary; or*

23 “(iii) *is a territory that receives less*
 24 *than \$1,000,000 for a fiscal year under sec-*
 25 *tion 1921.*

1 “(B) CERTIFICATION.—

2 “(i) IN GENERAL.—*The amount of*
3 *funds to be committed by a State pursuant*
4 *to subparagraph (A)(i) shall be equal to 1*
5 *percent of such State’s substance abuse allo-*
6 *cation determined under section 1933 for*
7 *each percentage point by which the State*
8 *misses the retailer compliance rate goal es-*
9 *tablished by the Secretary.*

10 “(ii) STATE EXPENDITURES.—*For a*
11 *fiscal year in which a State commits funds*
12 *as described in clause (i), such State shall*
13 *maintain State expenditures for tobacco*
14 *prevention programs and for compliance ac-*
15 *tivities at a level that is not less than the*
16 *level of such expenditures maintained by the*
17 *State for the preceding fiscal year, plus the*
18 *additional funds for tobacco compliance ac-*
19 *tivities required under clause (i). The State*
20 *shall submit a report to the Secretary on all*
21 *State obligations of funds for such fiscal*
22 *year and all State expenditures for the pre-*
23 *ceding fiscal year for tobacco prevention*
24 *and compliance activities by program activ-*
25 *ity by July 31 of such fiscal year.*

1 “(iii) *DISCRETION.*—*The Secretary*
 2 *shall exercise discretion in enforcing the*
 3 *timing of the State obligation of the addi-*
 4 *tional funds required by the certification*
 5 *described in subparagraph (A)(i) as late as*
 6 *July 31 of such fiscal year.*

7 “(C) *FAILURE TO CERTIFY.*—*If a State de-*
 8 *scribed in subparagraph (A) fails to certify to*
 9 *the Secretary pursuant to subparagraph (A)(i)*
 10 *or enter into, or comply with, a negotiated agree-*
 11 *ment under subparagraph (A)(ii), the Secretary*
 12 *may take action pursuant to paragraph (1).”;*
 13 *and*
 14 *(6) by adding at the end the following:*

15 “(c) *IMPLEMENTATION OF REPORTING REQUIRE-*
 16 *MENTS.*—

17 “(1) *TRANSITION PERIOD.*—*The Secretary*
 18 *shall—*

19 “(A) *not withhold amounts under subsection*
 20 *(b) for the 3-year period immediately following*
 21 *the date of enactment of the Lower Health Care*
 22 *Costs Act; and*

23 “(B) *use discretion in exercising its author-*
 24 *ity under subsection (b) during the 2-year period*
 25 *immediately following the 3-year period de-*

1 scribed in subparagraph (A), to allow for a tran-
 2 sition period for implementation of the reporting
 3 requirements under subsection (a)(2).

4 “(2) *REGULATIONS OR GUIDANCE.*—Not later
 5 than 180 days after the date of enactment of the
 6 Lower Health Care Costs Act the Secretary shall up-
 7 date regulations under part 96 of title 45, Code of
 8 Federal Regulations or guidance on the retailer com-
 9 pliance rate goal under subsection (b), the use of
 10 funds provided under section 1921 for purposes of
 11 meeting the requirements of this section, and report-
 12 ing requirements under subsection (a)(2).

13 “(3) *COORDINATION.*—The Secretary shall ensure
 14 the Assistant Secretary for Mental Health and Sub-
 15 stance Use coordinates, as appropriate, with the Com-
 16 missioner of Food and Drugs in providing technical
 17 assistance under this section to States, related to en-
 18 suring retailers do not sell tobacco products to indi-
 19 viduals under the age of 21, that is consistent with
 20 applicable regulations issued by the Food and Drug
 21 Administration.

22 “(d) *TRANSITIONAL GRANTS.*—

23 “(1) *IN GENERAL.*—The Secretary shall award
 24 grants under this subsection to each State that re-

1 *ceives funding under section 1921 to ensure compli-*
 2 *ance of each such State with this section.*

3 *“(2) USE OF FUNDS.—A State receiving a grant*
 4 *under this subsection—*

5 *“(A) shall use amounts received under such*
 6 *grant for activities to plan for or ensure compli-*
 7 *ance in the State with subsection (a); and*

8 *“(B) in the case of a State for which the*
 9 *Secretary has made a determination under sub-*
 10 *section (b) that the State is prepared to meet, or*
 11 *has met, the requirements of subsection (a), may*
 12 *use such funds for tobacco cessation activities,*
 13 *strategies to prevent the use of tobacco products*
 14 *by individuals under the age of 21, or allowable*
 15 *uses under section 1921.*

16 *“(3) SUPPLEMENT NOT SUPPLANT.—Grants*
 17 *under this subsection shall be used to supplement and*
 18 *not supplant other Federal, State, and local public*
 19 *funds provided for activities under paragraph (2).*

20 *“(4) AUTHORIZATION OF APPROPRIATIONS.—To*
 21 *carry out this subsection, there are authorized to be*
 22 *appropriated \$18,580,790 for each of fiscal years*
 23 *2020 through 2024.*

24 *“(5) SUNSET.—This subsection shall have no*
 25 *force or effect after September 30, 2024.*

1 “(e) *TECHNICAL ASSISTANCE.*—*The Secretary shall*
 2 *provide technical assistance to States related to the activi-*
 3 *ties required under this section.*”.

4 (b) *REPORT TO CONGRESS.*—*Not later than 3 years*
 5 *after the date of enactment of this Act, the Secretary shall*
 6 *submit to the Committee on Health, Education, Labor, and*
 7 *Pensions of the Senate and the Committee on Energy and*
 8 *Commerce of the House of Representatives a report on the*
 9 *status of implementing the requirements of section 1926 of*
 10 *the Public Health Service Act (42 U.S.C. 300x–26), as*
 11 *amended by subsection (a), and a description of any tech-*
 12 *nical assistance provided under subsection (e) of such sec-*
 13 *tion, including the number of meetings requested and held*
 14 *related to technical assistance.*

15 (c) *CONFORMING AMENDMENT.*—*Section 212 of divi-*
 16 *sion D of the Consolidated Appropriations Act, 2010 (Pub-*
 17 *lic Law 111–117) is repealed.*

18 ***TITLE V—IMPROVING THE EX-***
 19 ***CHANGE OF HEALTH INFOR-***
 20 ***MATION***

21 ***SEC. 501. REQUIREMENT TO PROVIDE HEALTH CLAIMS,***
 22 ***NETWORK, AND COST INFORMATION.***

23 (a) *IN GENERAL.*—*Part A of title XXVII of the Public*
 24 *Health Service Act (42 U.S.C. 300gg et seq.) is amended*
 25 *by inserting after section 2715A the following:*

1 **“SEC. 2715B. REQUIREMENT TO PROVIDE HEALTH CLAIMS,**
 2 **NETWORK, AND COST INFORMATION.**

3 “(a) *IN GENERAL.*—A group health plan or a health
 4 insurance issuer offering group or individual health insur-
 5 ance coverage shall make available for access, exchange, and
 6 use without special effort, through application program-
 7 ming interfaces (or successor technology or standards), the
 8 information described in subsection (b), in the manner de-
 9 scribed in subsection (b) and otherwise consistent with this
 10 section.

11 “(b) *INFORMATION.*—The following information is re-
 12 quired to be made available, as the Secretary may specify:

13 “(1) *Historical claims, provider encounter, and*
 14 *payment data for each enrollee, which shall—*

15 “(A) *include adjudicated medical and pre-*
 16 *scription drug claims and equivalent encounters,*
 17 *including all data elements contained in such*
 18 *transactions—*

19 “(i) *that were adjudicated by the group*
 20 *health plan or health insurance issuer dur-*
 21 *ing the previous 5 years or the enrollee’s en-*
 22 *tire period of enrollment in the applicable*
 23 *plan or coverage if such period is less than*
 24 *the previous 5 years;*

25 “(ii) *that involve benefits managed by*
 26 *any third party, such as a pharmacy bene-*

1 *fits manager or radiology benefits manager*
2 *that manages benefits or adjudicates claims*
3 *on behalf of the plan or coverage; and*

4 “(iii) *from any other health plan or*
5 *health insurance coverage offered by the*
6 *same insurance issuer, in which the same*
7 *enrollee was enrolled during the previous 5*
8 *years; and*

9 “(B) *be available to an enrollee or former*
10 *enrollee, the enrollee’s providers, and any third-*
11 *party applications or services authorized by the*
12 *enrollee—*

13 “(i) *through the application program-*
14 *ming interfaces (or successor technology or*
15 *standards) as required by this paragraph,*
16 *in a single, longitudinal format that is easy*
17 *to understand, secure, and that may update*
18 *automatically;*

19 “(ii) *as soon as practicable, and in no*
20 *case later than the period of time deter-*
21 *mined by the Secretary, after the claim is*
22 *adjudicated or the data is received by the*
23 *health plan or health insurance issuer; and*

24 “(iii) *to the enrollee, former enrollee,*
25 *and any providers or third-party applica-*

1 *tions or services authorized by the enrollee,*
 2 *for 5 years after the end date of the enroll-*
 3 *ee's enrollment in the plan or in any cov-*
 4 *erage offered by the health insurance issuer.*

5 *“(2) Identifying directory information for all in-*
 6 *network providers, including facilities and practi-*
 7 *tioners, that participate in the plan or coverage,*
 8 *which shall—*

9 *“(A) include—*

10 *“(i) the national provider identifier for*
 11 *in-network facilities and practitioners; and*

12 *“(ii) the name, address, phone number,*
 13 *and specialty for each such facility and*
 14 *practitioner, based on the most recent inter-*
 15 *action between the plan or coverage and*
 16 *that facility or practitioner;*

17 *“(B) be capable of returning the informa-*
 18 *tion necessary to establish a list of participating*
 19 *in-network facilities and practitioners, in a*
 20 *given specialty or at a particular facility type,*
 21 *within a specified geographic radius; and*

22 *“(C) be capable of returning the network*
 23 *status, when presented with identifiers for a*
 24 *given enrollee and facility or practitioner.*

1 “(3) *Estimated enrollee out-of-pocket costs, in-*
2 *cluding costs expected to be incurred through a de-*
3 *ductible, co-payment, coinsurance, or other form of*
4 *cost-sharing, for—*

5 “(A) *a designated set of common services or*
6 *episodes of care, to be established by the Sec-*
7 *retary through rulemaking, including, at a min-*
8 *imum—*

9 “(i) *in the case of services provided by*
10 *a hospital, the 100 most common diagnosis-*
11 *related groups, as used in the Medicare In-*
12 *patient Prospective Patient System (or suc-*
13 *cessor episode-based reimbursement method-*
14 *ology) at that hospital, based on claims*
15 *data adjudicated by the group health plan*
16 *or health insurance issuer;*

17 “(ii) *in the case of services provided in*
18 *an out-patient setting, including radiology,*
19 *lab tests, and out-patient surgical proce-*
20 *dures, any service rendered by the facility*
21 *or practitioner, and reimbursed by the*
22 *health plan or health insurance issuer; and*

23 “(iii) *in the case of post-acute care, in-*
24 *cluding home health providers, skilled nurs-*
25 *ing facilities, inpatient rehabilitation facili-*

1 *ties, and long-term care hospitals, the pa-*
 2 *tient out-of-pocket costs for an episode of*
 3 *care, as the Secretary may determine, which*
 4 *permits users to reasonably compare costs*
 5 *across different facility and service types;*
 6 *and*

7 *“(B) all prescription drugs currently in-*
 8 *cluded on any tier of the formulary of the plan*
 9 *or coverage.*

10 *“(4) A list of the categories of providers of ancil-*
 11 *lary services, as defined in section 2719(A)(i)(3), for*
 12 *which the plan or coverage has no in-network pro-*
 13 *viders.*

14 *“(c) AVAILABILITY AND ACCESS.—Subject to all appli-*
 15 *cable Federal and State privacy, security, and breach noti-*
 16 *fication laws, the application programming interfaces, in-*
 17 *cluding all data required to be made available through such*
 18 *interfaces, shall—*

19 *“(1) be made available by the applicable group*
 20 *health plan or health insurance issuer, at no charge,*
 21 *to—*

22 *“(A) enrollees and prospective enrollees in*
 23 *the group health plan or health insurance cov-*
 24 *erage;*

1 “(B) *third parties authorized by the en-*
2 *rollee;*

3 “(C) *facilities and practitioners who are*
4 *under contract with the plan or coverage; and*

5 “(D) *business associates of such facilities*
6 *and practitioners, as defined in section 160.103*
7 *of title 45, Code of Federal Regulations (or any*
8 *successor regulations);*

9 “(2) *be available to enrollees in the group health*
10 *plan or health insurance coverage, and to third-party*
11 *applications or services facilitating such access by en-*
12 *rollees, during the enrollment process and for a min-*
13 *imum of 5 years after the end date of the enrollee’s*
14 *enrollment in the plan or in any coverage offered by*
15 *the health insurance issuer;*

16 “(3) *permit persistent access by third party ap-*
17 *plications or services authorized by the enrollee, for a*
18 *reasonable period of time, consistent with the require-*
19 *ments of the HIPAA Security rule (part 160 of title*
20 *45 Code of Federal Regulations and subparts A and*
21 *C of part 164 of such title);*

22 “(4) *employ the applicable content, vocabulary,*
23 *and technical standards, as determined by the Sec-*
24 *retary pursuant to title XXX; and*

1 “(5) *employ security and authentication stand-*
 2 *ards, as the Secretary determines appropriate.*

3 “(d) *RULE OF CONSTRUCTION REGARDING PRIVACY.—*
 4 *Nothing in this section shall be construed to alter existing*
 5 *obligations of a covered entity or business associate under*
 6 *the privacy, security, and breach notification rules promul-*
 7 *gated under section 264(c) of the Health Insurance Port-*
 8 *ability and Accountability Act or section 13402 of the*
 9 *HITECH Act, or to alter the Secretary’s existing authority*
 10 *to modify such rules, under part 2 of title 42, Code of Fed-*
 11 *eral Regulations (or successor regulations), under section*
 12 *444 of the General Education Provisions Act (20 U.S.C.*
 13 *1232g) (commonly referred to as the ‘Family Educational*
 14 *Rights and Privacy Act of 1974’), under the amendments*
 15 *made by the Genetic Information Nondiscrimination Act,*
 16 *or under State privacy law.”.*

17 (b) *EFFECTIVE DATE.—Section 2715B of the Public*
 18 *Health Service Act, as added by subsection (a), shall take*
 19 *effect 18 months after the date of enactment of this Act.*

20 **SEC. 502. RECOGNITION OF SECURITY PRACTICES.**

21 *Part 1 of subtitle D of the Health Information Tech-*
 22 *nology for Economic and Clinical Health Act (42 U.S.C.*
 23 *17931 et seq.) is amended by adding at the end the fol-*
 24 *lowing:*

1 **“SEC. 13412. RECOGNITION OF SECURITY PRACTICES.**

2 “(a) *IN GENERAL.*—Consistent with the authority of
3 the Secretary under sections 1176 and 1177 of the Social
4 Security Act, when making determinations relating to fines
5 under section 13410, decreasing the length and extent of an
6 audit under section 13411, or remedies otherwise agreed to
7 by the Secretary, the Secretary shall consider whether the
8 covered entity or business associate has adequately dem-
9 onstrated that it had, for not less than the previous 12
10 months, recognized security practices in place that may—

11 “(1) mitigate fines under section 13410;

12 “(2) result in the early, favorable termination of
13 an audit under section 13411; and

14 “(3) mitigate the remedies that would otherwise
15 be agreed to in any agreement with respect to resolv-
16 ing potential violations of the HIPAA Security rule
17 (part 160 of title 45 Code of Federal Regulations and
18 subparts A and C of part 164 of such title) between
19 the covered entity or business associate and the De-
20 partment of Health and Human Services.

21 “(b) *DEFINITION AND MISCELLANEOUS PROVISIONS.*—

22 “(1) *RECOGNIZED SECURITY PRACTICES.*—The
23 term ‘recognized security practices’ means the stand-
24 ards, guidelines, best practices, methodologies, proce-
25 dures, and processes developed under section 2(c)(15)
26 of the National Institute of Standards and Technology

1 *Act, the approaches promulgated under section 405(d)*
 2 *of the Cybersecurity Act of 2015, and other programs*
 3 *and processes that address cybersecurity and that are*
 4 *developed, recognized, or promulgated through regula-*
 5 *tions under other statutory authorities. Such practices*
 6 *shall be determined by the covered entity or business*
 7 *associate.*

8 “(2) *LIMITATION.*—*Nothing in this section shall*
 9 *be construed as providing the Secretary authority to*
 10 *increase fines under section 13410, or the length, ex-*
 11 *tent or quantity of audits under section 13411, due*
 12 *to a lack of compliance with the recognized security*
 13 *practices.*

14 “(3) *NO LIABILITY FOR NONPARTICIPATION.*—
 15 *Subject to paragraph (4), nothing in this section shall*
 16 *be construed to subject a covered entity or business as-*
 17 *sociate to liability for electing not to engage in the*
 18 *recognized security practices defined by this section.*

19 “(4) *RULE OF CONSTRUCTION.*—*Nothing in this*
 20 *section shall be construed to limit the Secretary’s au-*
 21 *thority to enforce the HIPAA Security rule (part 160*
 22 *of title 45 Code of Federal Regulations and subparts*
 23 *A and C of part 164 of such title), or to supersede*
 24 *or conflict with an entity or business associate’s obli-*
 25 *gations under the HIPAA Security rule.”.*

1 **SEC. 503. GAO STUDY ON THE PRIVACY AND SECURITY**
2 **RISKS OF ELECTRONIC TRANSMISSION OF IN-**
3 **DIVIDUALLY IDENTIFIABLE HEALTH INFOR-**
4 **MATION TO AND FROM ENTITIES NOT COV-**
5 **ERED BY THE HEALTH INSURANCE PORT-**
6 **ABILITY AND ACCOUNTABILITY ACT.**

7 (a) *IN GENERAL.*—Not later than 1 year after the date
8 of enactment of this Act, the Comptroller General of the
9 United States shall conduct a study to—

10 (1) *describe the roles of Federal agencies and the*
11 *private sector with respect to protecting the privacy*
12 *and security of individually identifiable health infor-*
13 *mation transmitted electronically to and from entities*
14 *not covered by the regulations promulgated under sec-*
15 *tion 264(c) of the Health Insurance Portability and*
16 *Accountability Act of 1996 (42 U.S.C. 1320d–2 note);*

17 (2) *identify recent developments regarding the*
18 *use of application programming interfaces to access*
19 *individually identifiable health information, and im-*
20 *plications for the privacy and security of such infor-*
21 *mation;*

22 (3) *identify practices in the private sector, such*
23 *as terms and conditions for use, relating to the pri-*
24 *vacv, disclosure, and secondary uses of individually*
25 *identifiable health information transmitted electroni-*
26 *cally to or from entities, selected by an individual,*

1 that are not subject to the regulations promulgated
 2 under section 264(c) of the Health Insurance Port-
 3 ability and Accountability Act of 1996; and

4 (4) identify steps the public and private sectors
 5 can take to improve the private and secure access to
 6 and availability of individually identifiable health
 7 information.

8 (b) *REPORT*.—Not later than 1 year after the date of
 9 enactment of this Act, the Comptroller General of the United
 10 States shall submit to Congress a report concerning the
 11 findings of the study conducted under subsection (a).

12 **SEC. 504. TECHNICAL CORRECTIONS.**

13 (a) *IN GENERAL*.—Section 3022(b) of the Public
 14 Health Service Act (42 U.S.C. 300jj–52(b)) is amended by
 15 adding at the end the following new paragraph:

16 “(4) *APPLICATION OF AUTHORITIES UNDER IN-*
 17 *SPECTOR GENERAL ACT OF 1978*.—In carrying out
 18 this subsection, the Inspector General shall have the
 19 same authorities as provided under section 6 of the
 20 Inspector General Act of 1978 (5 U.S.C. App.).”.

21 (b) *EFFECTIVE DATE*.—The amendment made by sub-
 22 section (a) shall take effect as if included in the enactment
 23 of the 21st Century Cures Act (Public Law 114–255).

1 **SEC. 505. PUBLIC MEETING.**

2 (a) *IN GENERAL.*—Not later than 180 days after the
3 date of enactment of this Act, the Secretary of Health and
4 Human Services shall convene a public meeting for pur-
5 poses of discussing and providing input on patient-match-
6 ing metrics for the purpose of enabling interoperability and
7 the exchange of health information across health care orga-
8 nizations.

9 (b) *EXPERTS.*—The public meeting under this section
10 may include—

11 (1) *representatives of relevant Federal agencies*
12 *(including representatives from the Office of the Na-*
13 *tional Coordinator for Health Information Tech-*
14 *nology);*

15 (2) *State, local, Tribal, and territorial public*
16 *health officials;*

17 (3) *stakeholders with expertise in health informa-*
18 *tion exchange;*

19 (4) *stakeholders with expertise in capabilities*
20 *relevant to patient matching, such as experts in*
21 *informatics and data analytics;*

22 (5) *stakeholders affected by record-matching (in-*
23 *cluding patients, hospitals, health systems, payers,*
24 *health information exchanges, and prescription drug*
25 *monitoring programs); and*

1 (6) *other representatives, as the Secretary deter-*
2 *mines appropriate.*

3 (c) *TOPICS.*—*Such public meeting shall include a dis-*
4 *cussion of—*

5 (1) *standards and processes for assessing the ac-*
6 *curacy of patient-matching algorithms;*

7 (2) *performance metrics for health care providers*
8 *purchasing patient-matching technology and algo-*
9 *rithm developers;*

10 (3) *the development of benchmarks for the accu-*
11 *racy of patient-matching algorithms;*

12 (4) *considerations for State, local, Tribal, and*
13 *territorial capabilities and infrastructure related to*
14 *data exchange, interoperability, and matching patient*
15 *records;*

16 (5) *opportunities for the incorporation of inno-*
17 *vative technologies to improve patient matching; and*

18 (6) *privacy and security protections.*

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A BILL

To lower health care costs.

JULY 8, 2019

Reported with an amendment