

119TH CONGRESS
1ST SESSION

S. 891

To extend expiring health provisions and improve health care delivery.

IN THE SENATE OF THE UNITED STATES

MARCH 6, 2025

Mr. WYDEN (for himself and Mr. SANDERS) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To extend expiring health provisions and improve health care
delivery.

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 “Bipartisan Health Care 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—MEDICAID

Sec. 101. Streamlined enrollment process for eligible out-of-state providers
under Medicaid and CHIP.

Sec. 102. Making certain adjustments to coverage of home or community-based
services under Medicaid.

- Sec. 103. Removing certain age restrictions on Medicaid eligibility for working adults with disabilities.
- Sec. 104. Medicaid State plan requirement for determining residency and coverage for military families.
- Sec. 105. Ensuring the reliability of address information provided under the Medicaid program.
- Sec. 106. Codifying certain Medicaid provider screening requirements related to deceased providers.
- Sec. 107. Modifying certain State requirements for ensuring deceased individuals do not remain enrolled.
- Sec. 108. One-year delay of Medicaid and CHIP requirements for health screenings, referrals, and case management services for eligible juveniles in public institutions; State interim work plans.
- Sec. 109. State studies and HHS report on costs of providing maternity, labor, and delivery services.
- Sec. 110. Modifying certain disproportionate share hospital allotments.
- Sec. 111. Modifying certain limitations on disproportionate share hospital payment adjustments under the Medicaid program.
- Sec. 112. Ensuring accurate payments to pharmacies under Medicaid.
- Sec. 113. Preventing the use of abusive spread pricing in Medicaid.

TITLE II—MEDICARE

- Sec. 201. Extension of increased inpatient hospital payment adjustment for certain low-volume hospitals.
- Sec. 202. Extension of the Medicare-dependent hospital (MDH) program.
- Sec. 203. Extension of add-on payments for ambulance services.
- Sec. 204. Extending incentive payments for participation in eligible alternative payment models.
- Sec. 205. Temporary payment increase under the Medicare physician fee schedule to account for exceptional circumstances.
- Sec. 206. Extension of funding for quality measure endorsement, input, and selection.
- Sec. 207. Extension of funding outreach and assistance for low-income programs.
- Sec. 208. Extension of the work geographic index floor.
- Sec. 209. Extension of certain telehealth flexibilities.
- Sec. 210. Requiring modifier for use of telehealth to conduct face-to-face encounter prior to recertification of eligibility for hospice care.
- Sec. 211. Extending acute hospital care at home waiver flexibilities.
- Sec. 212. Enhancing certain program integrity requirements for DME under Medicare.
- Sec. 213. Guidance on furnishing services via telehealth to individuals with limited English proficiency.
- Sec. 214. In-home cardiopulmonary rehabilitation flexibilities.
- Sec. 215. Inclusion of virtual diabetes prevention program suppliers in MDPP Expanded Model.
- Sec. 216. Medication-induced movement disorder outreach and education.
- Sec. 217. Report on wearable medical devices.
- Sec. 218. Extension of temporary inclusion of authorized oral antiviral drugs as covered part D drugs.
- Sec. 219. Extension of adjustment to calculation of hospice cap amount.
- Sec. 220. Multiyear contracting authority for MedPAC and MACPAC.
- Sec. 221. Contracting parity for MedPAC and MACPAC.

- Sec. 222. Adjustments to Medicare part D cost-sharing reductions for low-income individuals.
- Sec. 223. Requiring Enhanced and Accurate Lists of (REAL) Health Providers Act.
- Sec. 224. Medicare coverage of multi-cancer early detection screening tests.
- Sec. 225. Medicare coverage of external infusion pumps and non-self-administrable home infusion drugs.
- Sec. 226. Assuring pharmacy access and choice for Medicare beneficiaries.
- Sec. 227. Modernizing and Ensuring PBM Accountability.
- Sec. 228. Requiring a separate identification number and an attestation for each off-campus outpatient department of a provider.
- Sec. 229. Medicare sequestration.
- Sec. 230. Medicare improvement fund.

TITLE III—HUMAN SERVICES

- Sec. 301. Sexual risk avoidance education extension.
- Sec. 302. Personal responsibility education extension.
- Sec. 303. Extension of funding for family-to-family health information centers.

TITLE IV—PUBLIC HEALTH EXTENDERS

Subtitle A—Extensions

- Sec. 401. Extension for community health centers, National Health Service Corps, and teaching health centers that operate GME programs.
- Sec. 402. Extension of special diabetes programs.

Subtitle B—World Trade Center Health Program

- Sec. 411. 9/11 responder and survivor health funding corrections.

TITLE V—SUPPORT ACT REAUTHORIZATION

- Sec. 501. Short title.

Subtitle A—Prevention

- Sec. 511. Prenatal and postnatal health.
- Sec. 512. Monitoring and education regarding infections associated with illicit drug use and other risk factors.
- Sec. 513. Preventing overdoses of controlled substances.
- Sec. 514. Support for individuals and families impacted by fetal alcohol spectrum disorder.
- Sec. 515. Promoting State choice in PDMP systems.
- Sec. 516. First responder training program.
- Sec. 517. Donald J. Cohen National Child Traumatic Stress Initiative.
- Sec. 518. Protecting suicide prevention lifeline from cybersecurity incidents.
- Sec. 519. Bruce's law.
- Sec. 520. Guidance on at-home drug disposal systems.
- Sec. 521. Assessment of opioid drugs and actions.
- Sec. 522. Grant program for State and Tribal response to opioid use disorders.

Subtitle B—Treatment

- Sec. 531. Residential treatment program for pregnant and postpartum women.
- Sec. 532. Improving access to addiction medicine providers.

- Sec. 533. Mental and behavioral health education and training grants.
- Sec. 534. Loan repayment program for substance use disorder treatment workforce.
- Sec. 535. Development and dissemination of model training programs for substance use disorder patient records.
- Sec. 536. Task force on best practices for trauma-informed identification, referral, and support.
- Sec. 537. Grants to enhance access to substance use disorder treatment.
- Sec. 538. State guidance related to individuals with serious mental illness and children with serious emotional disturbance.
- Sec. 539. Reviewing the scheduling of approved products containing a combination of buprenorphine and naloxone.

Subtitle C—Recovery

- Sec. 541. Building communities of recovery.
- Sec. 542. Peer support technical assistance center.
- Sec. 543. Comprehensive opioid recovery centers.
- Sec. 544. Youth prevention and recovery.
- Sec. 545. CAREER Act.
- Sec. 546. Addressing economic and workforce impacts of the opioid crisis.

Subtitle D—Miscellaneous Matters

- Sec. 551. Delivery of a controlled substance by a pharmacy to a prescribing practitioner.
- Sec. 552. Technical correction on controlled substances dispensing.
- Sec. 553. Required training for prescribers of controlled substances.
- Sec. 554. Extension of temporary order for fentanyl-related substances.

TITLE VI—PANDEMIC AND ALL-HAZARDS PREPAREDNESS AND RESPONSE

- Sec. 601. Short title.

Subtitle A—State and Local Readiness and Response

- Sec. 611. Temporary reassignment of State and local personnel during a public health emergency.
- Sec. 612. Public Health Emergency Preparedness program.
- Sec. 613. Hospital Preparedness Program.
- Sec. 614. Facilities and capacities of the Centers for Disease Control and Prevention to combat public health security threats.
- Sec. 615. Pilot program to support State medical stockpiles.
- Sec. 616. Enhancing domestic wastewater surveillance for pathogen detection.
- Sec. 617. Reauthorization of Mosquito Abatement for Safety and Health program.

Subtitle B—Federal Planning and Coordination

- Sec. 621. All-Hazards Emergency Preparedness and Response.
- Sec. 622. National Health Security Strategy.
- Sec. 623. Improving development and distribution of diagnostic tests.
- Sec. 624. Combating antimicrobial resistance.
- Sec. 625. Strategic National Stockpile and material threats.
- Sec. 626. Medical countermeasures for viral threats with pandemic potential.
- Sec. 627. Public Health Emergency Medical Countermeasures Enterprise.

- Sec. 628. Fellowship and training programs.
- Sec. 629. Regional biocontainment research laboratories.
- Sec. 629A. Limitation related to countries of concern conducting certain research.

Subtitle C—Addressing the Needs of All Individuals

- Sec. 631. Improving access to certain programs.
- Sec. 632. Supporting at-risk individuals during emergency responses.
- Sec. 633. National advisory committees.
- Sec. 634. National Academies study on prizes.

Subtitle D—Additional Reauthorizations

- Sec. 641. Medical countermeasure priority review voucher.
- Sec. 642. Epidemic Intelligence Service.
- Sec. 643. Monitoring and distribution of certain medical countermeasures.
- Sec. 644. Regional health care emergency preparedness and response systems.
- Sec. 645. Emergency system for advance registration of volunteer health professionals.
- Sec. 646. Ensuring collaboration and coordination in medical countermeasure development.
- Sec. 647. Military and civilian partnership for trauma readiness.
- Sec. 648. National Disaster Medical System.
- Sec. 649. Volunteer Medical Reserve Corps.
- Sec. 649A. Epidemiology-laboratory capacity.

TITLE VII—PUBLIC HEALTH PROGRAMS

- Sec. 701. Action for dental health.
- Sec. 702. PREEMIE.
- Sec. 703. Preventing maternal deaths.
- Sec. 704. Sickle cell disease prevention and treatment.
- Sec. 705. Traumatic brain injuries.
- Sec. 706. Lifespan respite care.
- Sec. 707. Dr. Lorna Breen health care provider protection.
- Sec. 708. SCREENS for Cancer.
- Sec. 709. DeOndra Dixon INCLUDE Project.
- Sec. 710. IMPROVE Initiative.
- Sec. 711. Organ Procurement and Transplantation Network.
- Sec. 712. Honor Our Living Donors.
- Sec. 713. Program for pediatric studies of drugs.

TITLE VIII—FOOD AND DRUG ADMINISTRATION

Subtitle A—Give Kids a Chance

- Sec. 801. Research into pediatric uses of drugs; additional authorities of Food and Drug Administration regarding molecularly targeted cancer drugs.
- Sec. 802. Ensuring completion of pediatric study requirements.
- Sec. 803. FDA report on PREA enforcement.
- Sec. 804. Extension of authority to issue priority review vouchers to encourage treatments for rare pediatric diseases.
- Sec. 805. Limitations on exclusive approval or licensure of orphan drugs.

Subtitle B—United States-Abraham Accords Cooperation and Security

Sec. 811. Establishment of Abraham Accords Office within Food and Drug Administration.

TITLE IX—LOWERING PRESCRIPTION DRUG COSTS

Sec. 901. Oversight of pharmacy benefit management services.

Sec. 902. Full rebate pass through to plan; exception for innocent plan fiduciaries.

Sec. 903. Increasing transparency in generic drug applications.

Sec. 904. Title 35 amendments.

TITLE X—MISCELLANEOUS

Sec. 1001. Extension of safe harbor for absence of deductible for telehealth.

TITLE I—MEDICAID

SEC. 101. STREAMLINED ENROLLMENT PROCESS FOR ELIGIBLE OUT-OF-STATE PROVIDERS UNDER MEDICAID AND CHIP.

(a) IN GENERAL.—Section 1902(kk) of the Social Security Act (42 U.S.C. 1396a(kk)) is amended by adding at the end the following new paragraph:

“(10) STREAMLINED ENROLLMENT PROCESS FOR ELIGIBLE OUT-OF-STATE PROVIDERS.—

“(A) IN GENERAL.—The State—

“(i) adopts and implements a process to allow an eligible out-of-State provider to enroll under the State plan (or a waiver of such plan) to furnish items and services to, or order, prescribe, refer, or certify eligibility for items and services for, qualifying individuals without the imposition of screening or enrollment requirements by such State that exceed the minimum nec-

1 essary for such State to provide payment
 2 to an eligible out-of-State provider under
 3 such State plan (or a waiver of such plan),
 4 such as the provider’s name and National
 5 Provider Identifier (and such other infor-
 6 mation specified by the Secretary); and

7 “(ii) provides that an eligible out-of-
 8 State provider that enrolls as a partici-
 9 pating provider in the State plan (or a
 10 waiver of such plan) through such process
 11 shall be so enrolled for a 5-year period, un-
 12 less the provider is terminated or excluded
 13 from participation during such period.

14 “(B) DEFINITIONS.—In this paragraph:

15 “(i) ELIGIBLE OUT-OF-STATE PRO-
 16 VIDER.—The term ‘eligible out-of-State
 17 provider’ means, with respect to a State, a
 18 provider—

19 “(I) that is located in any other
 20 State;

21 “(II) that—

22 “(aa) was determined by the
 23 Secretary to have a limited risk
 24 of fraud, waste, and abuse for
 25 purposes of determining the level

1 of screening to be conducted
2 under section 1866(j)(2), has
3 been so screened under such sec-
4 tion 1866(j)(2), and is enrolled in
5 the Medicare program under title
6 XVIII; or

7 “(bb) was determined by the
8 State agency administering or su-
9 pervising the administration of
10 the State plan (or a waiver of
11 such plan) of such other State to
12 have a limited risk of fraud,
13 waste, and abuse for purposes of
14 determining the level of screening
15 to be conducted under paragraph
16 (1) of this subsection, has been
17 so screened under such para-
18 graph (1), and is enrolled under
19 such State plan (or a waiver of
20 such plan); and

21 “(III) that has not been—

22 “(aa) excluded from partici-
23 pation in any Federal health care
24 program pursuant to section
25 1128 or 1128A;

“(bb) excluded from participation in the State plan (or a waiver of such plan) pursuant to part 1002 of title 42, Code of Federal Regulations (or any successor regulation), or State law; or

“(cc) terminated from participating in a Federal health care program or the State plan (or a waiver of such plan) for a reason described in paragraph (8)(A).

“(ii) QUALIFYING INDIVIDUAL.—The term ‘qualifying individual’ means an individual under 21 years of age who is enrolled under the State plan (or waiver of such plan).

“(iii) STATE.—The term ‘State’ means 1 of the 50 States or the District of Columbia.”.

(b) CONFORMING AMENDMENTS.—

(1) Section 1902(a)(77) of the Social Security Act (42 U.S.C. 1396a(a)(77)) is amended by inserting “enrollment,” after “screening,”.

1 (2) The subsection heading for section
 2 1902(kk) of such Act (42 U.S.C. 1396a(kk)) is
 3 amended by inserting “enrollment,” after “screen-
 4 ing,”.

5 (3) Section 2107(e)(1)(G) of such Act (42
 6 U.S.C. 1397gg(e)(1)(G)) is amended by inserting
 7 “enrollment,” after “screening,”.

8 (c) EFFECTIVE DATE.—The amendments made by
 9 this section shall take effect on the date that is 3 years
 10 after the date of enactment of this Act.

11 **SEC. 102. MAKING CERTAIN ADJUSTMENTS TO COVERAGE**
 12 **OF HOME OR COMMUNITY-BASED SERVICES**
 13 **UNDER MEDICAID.**

14 (a) INCREASING TRANSPARENCY OF HCBS COV-
 15 ERAGE UNDER MEDICAID.—

16 (1) IN GENERAL.—Section 1915(c) of the So-
 17 cial Security Act (42 U.S.C. 1396n(c)) is amend-
 18 ed—

19 (A) in paragraph (2)—

20 (i) in subparagraph (E)—

21 (I) by inserting “, not less fre-
 22 quently than” before “annually”; and

23 (II) by inserting “(including,
 24 with respect to such information pro-
 25 vided on or after July 9, 2027, the in-

1 formation specified in paragraph
2 (11))” before the period at the end;
3 and

4 (ii) by adding at the end the following
5 flush sentence:

6 “The Secretary shall make all information provided
7 under subparagraph (E) on or after the date of the
8 enactment of this sentence publicly available on the
9 website of the Centers for Medicare & Medicaid
10 Services.”; and

11 (B) by adding at the end the following new
12 paragraph:

13 “(11) For purposes of paragraph (2)(E), the
14 information specified in this paragraph is the fol-
15 lowing:

16 “(A) In the case of a State that limits the
17 number of individuals who may be provided
18 home or community-based services under a
19 waiver granted under this subsection and main-
20 tains a list of individuals waiting to enroll in
21 such waiver, a description of how the State
22 maintains such list, including—

23 “(i) information on whether the State
24 screens individuals on such list to deter-

1 mine whether such individuals are eligible
2 to receive such services under such waiver;

3 “(ii) information on whether (and, if
4 applicable, how often) the State periodi-
5 cally re-screens individuals on such list for
6 eligibility;

7 “(iii) the number of people on such
8 list of individuals waiting to enroll in such
9 waiver; and

10 “(iv) the average amount of time that
11 individuals newly enrolled in such waiver
12 within the past 12 months were on such
13 list of individuals waiting to enroll in such
14 waiver.

15 “(B) With respect to homemaker services,
16 home health aide services, personal care serv-
17 ices, and habilitation services furnished under
18 waivers under this subsection, by each such
19 service type—

20 “(i) for individuals newly receiving
21 such services within the past 12 months,
22 the average amount of time (which may be
23 determined using statistically valid random
24 sampling of such individuals) from when
25 such services are initially approved for

1 such an individual to when such individual
2 begins receiving such services; and

3 “(ii) the percentage of authorized
4 hours (which may be determined using sta-
5 tistically valid random sampling of individ-
6 uals authorized to receive such services)
7 that are provided within the past 12
8 months.”.

9 (2) CONFORMING AMENDMENTS.—Section 1915
10 of the Social Security Act (42 U.S.C. 1396n) is
11 amended—

12 (A) in subsection (i) by adding at the end
13 the following new paragraph:

14 “(8) REPORTING REQUIREMENT.—With respect
15 to homemaker services, home health aide services,
16 personal care services, and habilitation services pro-
17 vided under this subsection on or after July 9, 2027,
18 the State, not less frequently than annually, shall
19 provide to the Secretary the same information re-
20 garding such services as the State is required to pro-
21 vide under subsection (c)(11)(B).”;

22 (B) in subsection (j)(2)(E), by inserting
23 after the second sentence the following: “With
24 respect to any homemaker services, home health
25 aide services, personal care services, and habili-

tation services provided under this subsection on or after July 9, 2027, the State, not less frequently than annually, shall provide to the Secretary the same information regarding such services as the State is required to provide under subsection (c)(11)(B).”; and

(C) in subsection (k)(3)(E)—

(i) by striking “and” after “the cost of such services and supports,”; and

(ii) by inserting before the period, the following: “, and with respect to home-maker services, home health aide services, personal care services, and habilitation services provided under this subsection on or after July 9, 2027, not less frequently than annually, the same information regarding such services as the State is required to provide under subsection (c)(11)(B)”.

(b) DEMONSTRATION PROGRAM TO EXPAND HCBS COVERAGE UNDER SECTION 1915(C) WAIVERS.—Section 1915(c) of the Social Security Act (42 U.S.C. 1396n(c)), as amended by subsection (a), is further amended—

1 (1) in paragraph (2)(E), by inserting “, and the
 2 information specified in paragraph (12)(C)(v), when
 3 applicable” after “paragraph (11)”; and

4 (2) by adding at the end the following new
 5 paragraph:

6 “(12) DEMONSTRATION PROGRAM TO EXPAND
 7 COVERAGE FOR HOME OR COMMUNITY-BASED SERV-
 8 ICES.—

9 “(A) IN GENERAL.—

10 “(i) APPROVAL.—Not later than 24
 11 months after the date on which the plan-
 12 ning grants under subparagraph (B) are
 13 awarded, notwithstanding paragraph (1),
 14 the Secretary may approve a waiver that is
 15 standalone from any other waiver approved
 16 under this subsection for not more than 5
 17 States, selected in accordance with clause
 18 (ii), to include as medical assistance under
 19 the State plan of such State, for the 3-year
 20 period beginning on the date of such ap-
 21 proval, payment for part or all of the cost
 22 of home or community-based services
 23 (other than room and board (as described
 24 in paragraph (1))) approved by the Sec-
 25 retary which are provided pursuant to a

1 written plan of care to individuals de-
2 scribed in subparagraph (C)(iii).

3 “(ii) SELECTION CRITERIA.—In se-
4 lecting States for purposes of clause (i),
5 the Secretary shall—

6 “(I) only select States that re-
7 ceived a planning grant under sub-
8 paragraph (B);

9 “(II) only select States that meet
10 the requirements specified in subpara-
11 graph (C) and such other require-
12 ments as the Secretary may determine
13 appropriate;

14 “(III) select States in a manner
15 that ensures geographic diversity;

16 “(IV) give preference to States
17 with a higher percentage (relative to
18 other States that apply to be selected
19 for purposes of clause (i)) of the total
20 State population residing in rural
21 areas (as determined by the Sec-
22 retary);

23 “(V) give preference to States
24 that have demonstrated more progress
25 in rebalancing long-term services and

1 supports systems under this title, as
 2 determined based on the relative share
 3 of individuals who use home or com-
 4 munity-based services (as defined by
 5 the Secretary) under this title as a
 6 percentage of total individuals who
 7 use long-term services and supports
 8 (as defined by the Secretary) under
 9 this title (in the most recent year for
 10 which such data is available); and

11 “(VI) give preference to States
 12 that pursue a waiver under this para-
 13 graph that incorporates the provision
 14 of mental health services for adults
 15 with serious mental illness, children
 16 with serious emotional disturbances,
 17 or individuals with substance use dis-
 18 order.

19 “(B) PLANNING GRANTS.—

20 “(i) IN GENERAL.—

21 “(I) APPROVAL.—Not later than
 22 18 months after the date of the enact-
 23 ment of this paragraph, the Secretary
 24 shall award planning grants of not
 25 more than \$5,000,000 each to not

1 more than 10 States for purposes of
2 preparing to submit a request for a
3 waiver under this subsection (includ-
4 ing for costs to implement the waiver
5 or other activities to expand the provi-
6 sion of home or community-based
7 services under this section) to provide
8 home or community-based services to
9 individuals described in subparagraph
10 (C)(iii).

11 “(II) SELECTION CRITERIA.—In
12 awarding planning grants under sub-
13 clause (I), the Secretary shall use the
14 selection criteria specified in sub-
15 clauses (III) through (VI) of subpara-
16 graph (A)(ii).

17 “(ii) CONSULTATION.—A State that is
18 awarded a planning grant under clause (i)
19 shall, in preparing to submit a request for
20 a waiver described in such clause, consult
21 with—

22 “(I) individuals in need of (and
23 not receiving) home or community-
24 based services, individuals receiving

1 home or community-based services,
2 and the caregivers of such individuals;
3 “(II) providers furnishing home
4 or community-based services; and
5 “(III) such other stakeholders, as
6 the Secretary may specify.

7 “(C) STATE REQUIREMENTS.—In addition
8 to the requirements specified under this sub-
9 section (except for the requirements described
10 in subparagraphs (C) and (D) of paragraph (2)
11 and any other requirement the Secretary deter-
12 mines to be inapplicable in the context of a
13 waiver relation to individuals who do not re-
14 quire the level of care described in paragraph
15 (1)), the requirements specified in this para-
16 graph are, with respect to a State, the fol-
17 lowing:

18 “(i) As of the date that such State re-
19 quests a waiver under this subsection to
20 provide home or community-based services
21 to individuals described in clause (iii), all
22 other waivers (if any) granted under this
23 subsection to such State meet the require-
24 ments of this subsection.

1 “(ii) The State demonstrates to the
2 Secretary that approval of a waiver under
3 this subsection with respect to individuals
4 described in clause (iii) will not result in a
5 material increase of the average amount of
6 time that individuals with respect to whom
7 a determination described in paragraph (1)
8 has been made will need to wait to receive
9 home or community-based services under
10 any waiver granted under this subsection,
11 as determined by the Secretary.

12 “(iii) The State establishes needs-
13 based criteria, subject to the approval of
14 the Secretary, to identify individuals for
15 whom a determination described in para-
16 graph (1) is not applicable, who will be eli-
17 gible for home or community-based serv-
18 ices under a waiver approved under this
19 paragraph, and specifies the home or com-
20 munity-based services such individuals so
21 eligible will receive.

22 “(iv) The State established needs-
23 based criteria for determining whether an
24 individual described in clause (iii) requires
25 the level of care provided in a hospital,

1 nursing facility, or an intermediate care fa-
2 cility for individuals with developmental
3 disabilities under the State plan or under
4 any waiver of such plan that are more
5 stringent than the needs-based criteria es-
6 tablished under clause (iii) for determining
7 eligibility for home or community-based
8 services.

9 “(v) The State attests that the State’s
10 average per capita expenditure for medical
11 assistance under the State plan (or waiver
12 of such plan) provided with respect to such
13 individuals enrolled in a waiver under this
14 paragraph will not exceed the State’s aver-
15 age per capita expenditures for medical as-
16 sistance for individuals receiving institu-
17 tional care under the State plan (or waiver
18 of such plan) for the duration that the
19 waiver under this paragraph is in effect.

20 “(vi) The State provides to the Sec-
21 retary data (in such form and manner as
22 the Secretary may specify) regarding the
23 number of individuals described in clause
24 (i) with respect to a State seeking approval
25 of a waiver under this subsection, to whom

1 the State will make such services available
2 under such waiver.

3 “(vii) The State agrees to provide to
4 the Secretary, not less frequently than an-
5 nually, data for purposes of paragraph
6 (2)(E) (in such form and manner as the
7 Secretary may specify) regarding, with re-
8 spect to each preceding year in which a
9 waiver under this subsection to provide
10 home and community-based services to in-
11 dividuals described in clause (iii) was in ef-
12 fect—

13 “(I) the cost (as such term is de-
14 fined by the Secretary) of such serv-
15 ices furnished to individuals described
16 in clause (iii), broken down by type of
17 service;

18 “(II) with respect to each type of
19 home and community-based service
20 provided under the waiver, the length
21 of time that such individuals have re-
22 ceived such service;

23 “(III) a comparison between the
24 data described in subclause (I) and
25 any comparable data available with

1 respect to individuals with respect to
2 whom a determination described in
3 paragraph (1) has been made and
4 with respect to individuals receiving
5 institutional care under this title; and
6 “(IV) the number of individuals
7 who have received home and commu-
8 nity-based services under the waiver
9 during the preceding year.”.

10 (c) NON-APPLICATION OF THE PAPERWORK REDUC-
11 TION ACT.—Chapter 35 of title 44, United States Code
12 (commonly referred to as the “Paperwork Reduction Act
13 of 1995”), shall not apply to the implementation of the
14 amendments made by subsections (a) and (b).

15 (d) CMS GUIDANCE TO STATES ON INTERIM COV-
16 ERAGE UNDER SECTION 1915 HOME AND COMMUNITY-
17 BASED SERVICES AUTHORITIES.—Not later than January
18 1, 2027, the Secretary of Health and Human Services
19 shall issue guidance to the States to clarify how a State
20 may provide, with respect to an individual who is eligible
21 for home and community-based services under section
22 1915 of the Social Security Act (42 U.S.C. 1396n), cov-
23 erage of such services pursuant to a provisional written
24 plan of care, pending finalization, with respect to such in-
25 dividual.

1 (e) FUNDING.—

2 (1) IN GENERAL.—There are appropriated, out
 3 of any funds in the Treasury not otherwise obli-
 4 gated, \$71,000,000 for fiscal year 2025, to remain
 5 available until expended, to the Secretary of Health
 6 and Human Services for purposes of carrying out
 7 subsection (d) and the amendments made by sub-
 8 section (b).

9 (2) RESERVATION FOR PLANNING GRANTS.—Of
 10 the amount appropriated under paragraph (1), the
 11 Secretary of Health and Human Services shall re-
 12 serve \$50,000,000 of such amount to award plan-
 13 ning grants under the demonstration program estab-
 14 lished by the amendments made by subsection (b).

15 **SEC. 103. REMOVING CERTAIN AGE RESTRICTIONS ON MED-**
 16 **ICAID ELIGIBILITY FOR WORKING ADULTS**
 17 **WITH DISABILITIES.**

18 (a) MODIFICATION OF OPTIONAL BUY-IN GROUPS.—

19 (1) IN GENERAL.—Section
 20 1902(a)(10)(A)(ii)(XV) of the Social Security Act
 21 (42 U.S.C. 1396a(a)(10)(A)(ii)(XV)) is amended by
 22 striking “but less than 65,”.

23 (2) DEFINITION MODIFICATION.—Section
 24 1905(v)(1)(A) of the Social Security Act (42 U.S.C.

14 **SEC. 104. MEDICAID STATE PLAN REQUIREMENT FOR DE-**
15 **TERMINING RESIDENCY AND COVERAGE FOR**
16 **MILITARY FAMILIES.**

19 (1) in subsection (a)—

(B) in paragraph (87), by striking the period at the end and inserting “; and”; and

(C) by inserting after paragraph (87), the following new paragraph:

1 “(88) beginning January 1, 2028, provide, with
2 respect to an active duty relocated individual (as de-
3 fined in subsection (uu)(1))—

4 “(A) that, for purposes of determining eli-
5 gibility for medical assistance under the State
6 plan (or waiver of such plan), such active duty
7 relocated individual is treated as a resident of
8 the State unless such individual voluntarily
9 elects not to be so treated for such purposes;

10 “(B) that if, at the time of relocation (as
11 described in subsection (uu)(1)), such active
12 duty relocated individual is on a home and com-
13 munity-based services waiting list (as defined in
14 subsection (uu)(2)), such individual remains on
15 such list until—

16 “(i) the State completes an assess-
17 ment and renders a decision with respect
18 to the eligibility of such individual to re-
19 ceive the relevant home and community-
20 based services at the time a slot for such
21 services becomes available and, in the case
22 such decision is a denial of such eligibility,
23 such individual has exhausted the individ-
24 ual’s opportunity for a fair hearing; or

1 “(ii) such individual elects to be re-
2 moved from such list; and

3 “(C) payment for medical assistance fur-
4 nished under the State plan (or a waiver of the
5 plan) on behalf of such active duty relocated in-
6 dividual in the military service relocation State
7 (as referred to in subsection (uu)(1)(B)(i)), to
8 the extent that such assistance is available in
9 such military service relocation State in accord-
10 ance with such guidance as the Secretary may
11 issue to ensure access to such assistance.”; and
12 (2) by adding at the end the following new sub-
13 section:

14 “(uu) ACTIVE DUTY RELOCATED INDIVIDUAL; HOME
15 AND COMMUNITY-BASED SERVICES WAITING LIST.—For
16 purposes of subsection (a)(88) and this subsection:

17 “(1) ACTIVE DUTY RELOCATED INDIVIDUAL.—
18 The term ‘active duty relocated individual’ means an
19 individual—

20 “(A) who—

21 “(i) is enrolled under the State plan
22 (or waiver of such plan); or

23 “(ii) with respect to an individual de-
24 scribed in subparagraph (C)(ii), would be
25 so enrolled pursuant to subsection

1 (a)(10)(A)(ii)(VI) if such individual began
2 receiving home and community-based serv-
3 ices;

4 “(B) who—

5 “(i) is a member of the Armed Forces
6 engaged in active duty service and is relo-
7 cated to another State (in this subsection
8 referred to as the ‘military service reloca-
9 tion State’) by reason of such service;

10 “(ii) would be described in clause (i)
11 except that the individual stopped being
12 engaged in active duty service (including
13 by reason of retirement from such service)
14 and the last day on which the individual
15 was engaged in active duty service oc-
16 curred not more than 12 months ago; or

17 “(iii) is a dependent (as defined by
18 the Secretary) of a member described in
19 clause (i) or (ii) who relocates to the mili-
20 tary service relocation State with such
21 member; and

22 “(C) who—

23 “(i) was receiving home and commu-
24 nity-based services (as defined in section
25 9817(a)(2)(B) of the American Rescue

1 Plan Act of 2021) at the time of such relo-
 2 cation; or

3 “(ii) if the State maintains a home
 4 and community-based services waiting list,
 5 was on such home and community-based
 6 services waiting list at the time of such re-
 7 location.

8 “(2) HOME AND COMMUNITY-BASED SERVICES
 9 WAITING LIST.—The term ‘home and community-
 10 based services waiting list’ means, in the case of a
 11 State that has a limit on the number of individuals
 12 who may receive home and community-based services
 13 under section 1115(a), section 1915(c), or section
 14 1915(j), a list maintained by such State of individ-
 15 uals who are requesting to receive such services
 16 under 1 or more such sections but for whom the
 17 State has not yet completed an assessment and ren-
 18 dered a decision with respect to the eligibility of
 19 such individuals to receive the relevant home and
 20 community-based services at the time a slot for such
 21 services becomes available due to such limit.”.

22 (b) IMPLEMENTATION FUNDING.—There are appro-
 23 priated, out of any funds in the Treasury not otherwise
 24 obligated, \$1,000,000 for each of fiscal years 2025
 25 through 2029, to remain available until expended, to the

1 Secretary of Health and Human Services for purposes of
 2 implementing the amendments made by subsection (a).

3 **SEC. 105. ENSURING THE RELIABILITY OF ADDRESS INFOR-**
 4 **MATION PROVIDED UNDER THE MEDICAID**
 5 **PROGRAM.**

6 (a) IN GENERAL.—Section 1902(a) of the Social Se-
 7 curity Act (42 U.S.C. 1396a(a)), as previously amended
 8 by this title, is amended—

9 (1) in paragraph (87), by striking “and” at the
 10 end;

11 (2) in paragraph (88), by striking the period at
 12 the end and inserting “; and”; and

13 (3) by inserting after paragraph (88) the fol-
 14 lowing new paragraph:

15 “(89) beginning January 1, 2026, provide for a
 16 process to regularly obtain address information for
 17 individuals enrolled under such plan (or a waiver of
 18 such plan) from reliable data sources (as described
 19 in section 435.919(f)(1)(iii) of title 42, Code of Fed-
 20 eral Regulations (or a successor regulation)) and act
 21 on any changes to such an address based on such in-
 22 formation in accordance with such section (or suc-
 23 cessor regulation), except that this paragraph shall
 24 only apply in the case of the 50 States and the Dis-
 25 trict of Columbia.”.

1 (b) APPLICATION TO CHIP.—Section 2107(e)(1) of
 2 the Social Security Act (42 U.S.C. 1397gg(e)(1)) is
 3 amended—

4 (1) by redesignating subparagraphs (H)
 5 through (U) as subparagraphs (I) through (V), re-
 6 spectively; and

7 (2) by inserting after subparagraph (G) the fol-
 8 lowing new subparagraph:

9 “(H) Section 1902(a)(89) (relating to reg-
 10 ularly obtaining address information for enroll-
 11 ees).”.

12 (c) ENSURING TRANSMISSION OF ADDRESS INFOR-
 13 MATION FROM MANAGED CARE ORGANIZATIONS.—Sec-
 14 tion 1932 of the Social Security Act (42 U.S.C. 1396u-
 15 2) is amended by adding at the end the following new sub-
 16 section:

17 “(j) TRANSMISSION OF ADDRESS INFORMATION.—
 18 Beginning January 1, 2026, each contract under a State
 19 plan with a managed care entity under section 1903(m)
 20 shall provide that the entity transmits to the State any
 21 address information for an individual enrolled with the en-
 22 tity that is provided to such entity directly from, or
 23 verified by such entity directly with, such individual.”.

1 **SEC. 106. CODIFYING CERTAIN MEDICAID PROVIDER**
 2 **SCREENING REQUIREMENTS RELATED TO**
 3 **DECEASED PROVIDERS.**

4 Section 1902(kk)(1) of the Social Security Act (42
 5 U.S.C. 1396a(kk)(1)) is amended—

6 (1) by striking “The State” and inserting:

7 “(A) IN GENERAL.—The State”; and

8 (2) by adding at the end the following new sub-
 9 paragraph:

10 “(B) ADDITIONAL PROVIDER SCREEN-
 11 ING.—Beginning January 1, 2027, as part of
 12 the enrollment (or reenrollment or revalidation
 13 of enrollment) of a provider or supplier under
 14 this title, and not less frequently than quarterly
 15 during the period that such provider or supplier
 16 is so enrolled, the State conducts a check of the
 17 Death Master File (as such term is defined in
 18 section 203(d) of the Bipartisan Budget Act of
 19 2013) to determine whether such provider or
 20 supplier is deceased.”.

21 **SEC. 107. MODIFYING CERTAIN STATE REQUIREMENTS FOR**
 22 **ENSURING DECEASED INDIVIDUALS DO NOT**
 23 **REMAIN ENROLLED.**

24 Section 1902 of the Social Security Act (42 U.S.C.
 25 1396a), as previously amended by this title, is amended—

26 (1) in subsection (a)—

1 (A) in paragraph (88), by striking “; and”
 2 and inserting a semicolon;

3 (B) in paragraph (89), by striking the pe-
 4 riod at the end and inserting “; and”; and

5 (C) by inserting after paragraph (89) the
 6 following new paragraph:

7 “(90) provide that the State shall comply with
 8 the eligibility verification requirements under sub-
 9 section (vv), except that this paragraph shall apply
 10 only in the case of the 50 States and the District
 11 of Columbia.”; and

12 (2) by adding at the end the following new sub-
 13 section:

14 “(vv) VERIFICATION OF CERTAIN ELIGIBILITY CRI-
 15 TERIA.—

16 “(1) IN GENERAL.—For purposes of subsection
 17 (a)(90), the eligibility verification requirements, be-
 18 ginning January 1, 2026, are as follows:

19 “(A) QUARTERLY SCREENING TO VERIFY
 20 ENROLLEE STATUS.—The State shall, not less
 21 frequently than quarterly, review the Death
 22 Master File (as such term is defined in section
 23 203(d) of the Bipartisan Budget Act of 2013)
 24 to determine whether any individuals enrolled

1 for medical assistance under the State plan (or
2 waiver of such plan) are deceased.

3 “(B) DISENROLLMENT UNDER STATE
4 PLAN.—If the State determines, based on infor-
5 mation obtained from the Death Master File,
6 that an individual enrolled for medical assist-
7 ance under the State plan (or waiver of such
8 plan) is deceased, the State shall—

9 “(i) treat such information as factual
10 information confirming the death of a ben-
11 eficiary for purposes of section 431.213(a)
12 of title 42, Code of Federal Regulations (or
13 any successor regulation);

14 “(ii) disenroll such individual from the
15 State plan (or waiver of such plan); and

16 “(iii) discontinue any payments for
17 medical assistance under this title made on
18 behalf of such individual (other than pay-
19 ments for any items or services furnished
20 to such individual prior to the death of
21 such individual).

22 “(C) REINSTATEMENT OF COVERAGE IN
23 THE EVENT OF ERROR.—If a State determines
24 that an individual was misidentified as deceased
25 based on information obtained from the Death

1 Master File, and was erroneously disenrolled
 2 from medical assistance under the State plan
 3 (or waiver of such plan) based on such
 4 misidentification, the State shall immediately
 5 reenroll such individual under the State plan
 6 (or waiver of such plan), retroactive to the date
 7 of such disenrollment.

8 “(2) RULE OF CONSTRUCTION.—Nothing under
 9 this subsection shall be construed to preclude the
 10 ability of a State to use other electronic data sources
 11 to timely identify potentially deceased beneficiaries,
 12 so long as the State is also in compliance with the
 13 requirements of this subsection (and all other re-
 14 quirements under this title relating to Medicaid eli-
 15 gibility determination and redetermination).”.

16 **SEC. 108. ONE-YEAR DELAY OF MEDICAID AND CHIP RE-**
 17 **QUIREMENTS FOR HEALTH SCREENINGS, RE-**
 18 **FERRALS, AND CASE MANAGEMENT SERV-**
 19 **ICES FOR ELIGIBLE JUVENILES IN PUBLIC**
 20 **INSTITUTIONS; STATE INTERIM WORK PLANS.**

21 (a) IN GENERAL.—Section 5121(d) of subtitle C of
 22 title V of division FF of the Consolidated Appropriations
 23 Act, 2023 (Public Law 117–328) is amended—

24 (1) by striking “The amendments made by this
 25 section” and inserting the following:

1 “(1) IN GENERAL.—Subject to paragraph (2),
2 the amendments made by this section”; and

3 (2) by adding at the end the following new
4 paragraph:

5 “(2) DELAY OF DATE BY WHICH STATES MUST
6 COMPLY WITH CERTAIN JUVENILE JUSTICE-RE-
7 LATED REQUIREMENTS.—A State shall not be re-
8 garded as failing to comply with the requirements of
9 section 1902(a)(84)(D) or 2102(d)(2) of the Social
10 Security Act (42 U.S.C. 1396a(a)(84)(D),
11 1397bb(d)(2)) before January 1, 2026.”.

12 (b) CLARIFYING NONAPPLICATION OF REQUIRE-
13 MENTS TO INDIVIDUALS IN FEDERAL CUSTODY.—

14 (1) MEDICAID.—

15 (A) Subparagraph (D) of section
16 1902(a)(84) of the Social Security Act (42
17 U.S.C. 1396a(a)(84)), as added by section 5121
18 of subtitle C of title V of division FF of the
19 Consolidated Appropriations Act, 2023 (Public
20 Law 117–328), is amended by striking “an in-
21 dividual who is an eligible juvenile” and insert-
22 ing “an individual (other than an individual
23 who is in Federal custody, including as an in-
24 mate in a Federal prison) who is an eligible ju-
25 venile”.

1 (B) Section 5122(a) of subtitle C of title
2 V of division FF of the Consolidated Appropria-
3 tions Act, 2023 (Public Law 117–328) is
4 amended—

5 (i) by striking “paragraph (31)” each
6 place it appears and inserting “the last
7 numbered paragraph”; and

8 (ii) in paragraph (1), by striking “an
9 individual who is an eligible juvenile” and
10 inserting “an individual (other than an in-
11 dividual who is in Federal custody, includ-
12 ing as an inmate in a Federal prison) who
13 is an eligible juvenile”.

14 (2) CHIP.—

15 (A) Subsection (d)(2) of section 2102 of
16 the Social Security Act (42 U.S.C. 1397bb), as
17 added by section 5121 of subtitle C of title V
18 of division FF of the Consolidated Appropria-
19 tions Act, 2023 (Public Law 117–328), is
20 amended by striking “a targeted low-income
21 child who” and inserting “a targeted low in-
22 come child (other than a child who is in Federal
23 custody, including as an inmate in a Federal
24 prison) who”.

1 (B) Section 5122(b)(2) of subtitle C of
2 title V of division FF of the Consolidated Ap-
3 propriations Act, 2023 (Public Law 117–328)
4 is amended by striking “a child who is” and in-
5 serting “a child (other than a child who is in
6 Federal custody, including as an inmate in a
7 Federal prison) who is”.

8 (3) EFFECTIVE DATE.—The amendments made
9 by this subsection shall take effect as if enacted on
10 December 29, 2022.

11 (c) INTERIM WORK PLAN.—Not later than June 30,
12 2025, each State (as such term is defined in section
13 1101(a)(1) of the Social Security Act (42 U.S.C.
14 1301(a)(1)) for purposes of titles XIX and XXI of such
15 Act) shall submit to the Secretary of Health and Human
16 Services an interim work plan, in such form and con-
17 taining such information as the Secretary may specify, de-
18 scribing the State’s progress towards implementing, and
19 its plans to come into compliance with, the requirements
20 imposed by the amendments made by section 5121 of sub-
21 title C of title V of division FF of the Consolidated Appro-
22 priations Act, 2023 (Public Law 117–328), consistent
23 with the guidance issued by the Centers for Medicare &
24 Medicaid Services in State Health Official Letter #24–
25 004 on July 23, 2024.

1 **SEC. 109. STATE STUDIES AND HHS REPORT ON COSTS OF**
2 **PROVIDING MATERNITY, LABOR, AND DELIV-**
3 **ERY SERVICES.**

4 (a) STATE STUDY.—

5 (1) IN GENERAL.—Not later than 24 months
6 after the date of enactment of this Act, and every
7 5 years thereafter, each State (as such term is de-
8 fined in section 1101(a)(1) of the Social Security
9 Act (42 U.S.C. 1301(a)(1)) for purposes of titles
10 XIX and XXI of such Act) shall conduct a study on
11 the costs of providing maternity, labor, and delivery
12 services in applicable hospitals (as defined in para-
13 graph (3)) and submit the results of such study to
14 the Secretary of Health and Human Services (re-
15 ferred to in this section as the “Secretary”).

16 (2) CONTENT OF STUDY.—A State study re-
17 quired under paragraph (1) shall include the fol-
18 lowing information (to the extent practicable) with
19 respect to maternity, labor, and delivery services fur-
20 nished by applicable hospitals located in the State:

21 (A) An estimate of the cost of providing
22 maternity, labor, and delivery services at appli-
23 cable hospitals, based on the expenditures a
24 representative sample of such hospitals incurred
25 for providing such services during the 2 most
26 recent years for which data is available.

1 (B) An estimate of the cost of providing
2 maternity, labor, and delivery services at appli-
3 cable hospitals that ceased providing labor and
4 delivery services within the past 5 years, based
5 on the expenditures a representative sample of
6 such hospitals incurred for providing such serv-
7 ices during the 2 most recent years for which
8 data is available.

9 (C) To the extent data allows, an analysis
10 of the extent to which geographic location, com-
11 munity demographics, and local economic fac-
12 tors (as defined by the Secretary) affect the
13 cost of providing maternity, labor, and delivery
14 services at applicable hospitals, including the
15 cost of services that support the provision of
16 maternity, labor, and delivery services.

17 (D) The amounts applicable hospitals are
18 paid for maternity, labor, and delivery services,
19 by geographic location and hospital size,
20 under—

21 (i) Medicare;

22 (ii) the State Medicaid program, in-
23 cluding payment amounts for such services
24 under fee-for-service payment arrange-

1 ments and under managed care (as appli-
2 cable);

3 (iii) the State CHIP plan, including
4 payment amounts for such services under
5 fee-for-service payment arrangements and
6 under managed care (as applicable); and

7 (iv) private health insurance.

8 (E) A comparative payment rate anal-
9 ysis—

10 (i) comparing payment rates for ma-
11 ternity, labor, and delivery services (inclu-
12 sive of all payments received by applicable
13 hospitals for furnishing maternity, labor,
14 and delivery services) under the State
15 Medicaid fee-for-service program to such
16 payment rates for such services under
17 Medicare (as described in section
18 447.203(b)(3) of title 42, Code of Federal
19 Regulations), other Federally-funded or
20 State-funded programs (including, to the
21 extent data is available, Medicaid managed
22 care rates), and to the payment rates for
23 such services, to the extent data is avail-
24 able, of private health insurers within geo-
25 graphic areas of the State; and

1 (ii) analyzing different payment meth-
 2 ods for such services, such as the use of
 3 bundled payments, quality incentives, and
 4 low-volume adjustments.

5 (F) An evaluation, using such methodology
 6 and parameters established by the Secretary, of
 7 whether each hospital located in the State that
 8 furnishes maternity, labor, and delivery services
 9 is expected to experience in the next 3 years
 10 significant changes in particular expenditures
 11 or types of reimbursement for maternity, labor,
 12 and delivery services.

13 (3) APPLICABLE HOSPITAL DEFINED.—For
 14 purposes of this subsection, the term “applicable
 15 hospital” means any hospital located in a State that
 16 meets either of the following criteria:

17 (A) The hospital provides labor and deliv-
 18 ery services and more than 50 percent of the
 19 hospital’s births (in the most recent year for
 20 which such data is available) are financed by
 21 the Medicaid program or CHIP.

22 (B) The hospital—

23 (i) is located in a rural area (as de-
 24 fined by the Federal Office of Rural
 25 Health Policy for the purpose of rural

1 health grant programs administered by
2 such Office);

3 (ii) based on the most recent 2 years
4 of data available (as determined by the
5 Secretary), furnished services for less than
6 an average of 300 births per year; and

7 (iii) provides labor and delivery serv-
8 ices.

9 (4) ASSISTANCE TO SMALL HOSPITALS IN COM-
10 PILING COST INFORMATION.—There are appro-
11 priated to the Secretary for fiscal year 2025,
12 \$10,000,000 for the purpose of providing grants and
13 technical assistance to a hospital described in para-
14 graph (3)(B) to enable such hospital to compile de-
15 tailed information for use in the State studies re-
16 quired under paragraph (1), to remain available
17 until expended.

18 (5) HHS REPORT ON STATE STUDIES.—For
19 each year in which a State is required to conduct a
20 study under paragraph (1), the Secretary shall issue,
21 not later than 12 months after the date on which
22 the State submits to the Secretary the data de-
23 scribed in such paragraph, a publicly available re-
24 port that compiles and details the results of such

1 study and includes the information described in
2 paragraph (2).

3 (b) HHS REPORT ON NATIONAL DATA COLLECTION
4 FINDINGS.—Not later than 3 years after the date of en-
5 actment of this Act, the Secretary shall submit to Con-
6 gress, and make publicly available, a report analyzing the
7 first studies conducted by States under subsection (a)(1),
8 including recommendations for improving data collection
9 on the cost of providing maternity, labor, and delivery
10 services.

11 (c) IMPLEMENTATION FUNDING.—In addition to the
12 amount appropriated under subsection (a)(4), there are
13 appropriated, out of any funds in the Treasury not other-
14 wise obligated, \$3,000,000 for fiscal year 2025, to remain
15 available until expended, to the Secretary of Health and
16 Human Services for purposes of implementing this sec-
17 tion.

18 **SEC. 110. MODIFYING CERTAIN DISPROPORTIONATE SHARE**
19 **HOSPITAL ALLOTMENTS.**

20 (a) EXTENDING TENNESSEE DSH ALLOTMENTS.—
21 Section 1923(f)(6)(A)(vi) of the Social Security Act (42
22 U.S.C. 1396r–4(f)(6)(A)(vi)) is amended—

23 (1) in the heading, by striking “2025” and in-
24 serting “2026 AND FOR THE 1ST QUARTER OF FISCAL
25 YEAR 2027”;

1 (2) by striking “fiscal year 2025” and inserting
2 “fiscal year 2026”; and

3 (3) by inserting “, and the DSH allotment for
4 Tennessee for the 1st quarter of fiscal year 2027,
5 shall be \$13,275,000” before the period.

6 (b) ELIMINATING AND DELAYING DSH ALLOTMENT
7 REDUCTIONS.—Section 1923(f) of the Social Security Act
8 (42 U.S.C. 1396r–4(f)) is amended—

9 (1) in paragraph (7)(A)—

10 (A) in clause (i), in the matter preceding
11 subclause (I), by striking “April 1, 2025,” and
12 all that follows through “2027” and inserting
13 “January 1, 2027, and ending September 30,
14 2027, and for fiscal year 2028”; and

15 (B) in clause (ii), by striking “April 1,
16 2025,” and all that follows through “2027” and
17 inserting “January 1, 2027, and ending Sep-
18 tember 30, 2027, and for fiscal year 2028”;
19 and

20 (2) in paragraph (8), by striking “2027” and
21 inserting “2028”.

1 **SEC. 111. MODIFYING CERTAIN LIMITATIONS ON DIS-**
 2 **PROPORTIONATE SHARE HOSPITAL PAY-**
 3 **MENT ADJUSTMENTS UNDER THE MEDICAID**
 4 **PROGRAM.**

5 (a) IN GENERAL.—Section 1923(g) of the Social Se-
 6 curity Act (42 U.S.C. 1396r-4(g)) is amended—

7 (1) in paragraph (1)—

8 (A) in subparagraph (A)—

9 (i) in the matter preceding clause (i),
 10 by striking “(other than a hospital de-
 11 scribed in paragraph (2)(B))”;

12 (ii) in clause (i), by inserting “with
 13 respect to such hospital and year” after
 14 “described in subparagraph (B)”; and

15 (iii) in clause (ii)—

16 (I) in subclause (I), by striking
 17 “and” at the end;

18 (II) in subclause (II), by striking
 19 the period and inserting “; and”; and

20 (III) by adding at the end the
 21 following new subclause:

22 “(III) payments made under title
 23 XVIII or by an applicable plan (as de-
 24 fined in section 1862(b)(8)(F)) for
 25 such services.”; and

26 (B) in subparagraph (B)—

1 (i) in the matter preceding clause (i),
2 by striking “in this clause are” and insert-
3 ing “in this subparagraph are, with respect
4 to a hospital and a year,”; and

5 (ii) by adding at the end the following
6 new clause:

7 “(iii) Individuals who are eligible for
8 medical assistance under the State plan or
9 under a waiver of such plan and for whom
10 the State plan or waiver is a payor for
11 such services after application of benefits
12 under title XVIII or under an applicable
13 plan (as defined in section 1862(b)(8)(F)),
14 but only if the hospital has in the aggre-
15 gate incurred costs exceeding payments
16 under such State plan, waiver, title XVIII,
17 or applicable plan for such services fur-
18 nished to such individuals during such
19 year.”;

20 (2) by striking paragraph (2);

21 (3) by redesignating paragraph (3) as para-
22 graph (2); and

23 (4) in paragraph (2), as so redesignated, by
24 striking “Notwithstanding paragraph (2) of this

1 subsection (as in effect on October 1, 2021), para-
 2 graph (2)” and inserting “Paragraph (2)”.

3 (b) EFFECTIVE DATE.—

4 (1) IN GENERAL.—Except as provided in para-
 5 graph (2), the amendments made by this section
 6 shall apply to payment adjustments made under sec-
 7 tion 1923 of the Social Security Act (42 U.S.C.
 8 1396r–4) for Medicaid State plan rate years begin-
 9 ning on or after the date of enactment of this Act.

10 (2) STATE OPTION TO DISTRIBUTE UNSPENT
 11 DSH ALLOTMENTS FROM PRIOR YEARS UP TO MODI-
 12 FIED CAP.—

13 (A) IN GENERAL.—If, for any Medicaid
 14 State plan rate year that begins on or after Oc-
 15 tober 1, 2021, and before the date of enactment
 16 of this Act, a State did not spend the full
 17 amount of its Federal fiscal year allotment
 18 under section 1923 of the Social Security Act
 19 (42 U.S.C. 1396r–4) applicable to that State
 20 plan rate year, the State may use the unspent
 21 portion of such allotment to increase the
 22 amount of any payment adjustment made to a
 23 hospital for such rate year, provided that—

24 (i) such payment adjustment (as so
 25 increased) is consistent with subsection (g)

of such section (as amended by this section); and

(ii) the total amount of all payment adjustments for the State plan rate year (as so increased) does not exceed the proportionate share hospital allotment for the State and applicable Federal fiscal year under subsection (f) of such section.

(B) NO RECOUPMENT OF PAYMENTS ALREADY MADE TO HOSPITALS.—A State shall not recoup any payment adjustment made by the State to a hospital for a Medicaid State plan rate year described in subparagraph (A) if such payment adjustment is consistent with section 1923(g) of such Act (42 U.S.C. 1396r-4(g)) as in effect on October 1, 2021.

(C) AUTHORITY TO PERMIT RETROACTIVE MODIFICATION OF STATE PLAN AMENDMENTS TO ALLOW FOR INCREASES.—

(i) IN GENERAL.—Subject to paragraph (2), solely for the purpose of allowing a State to increase the amount of a payment adjustment to a hospital for a Medicaid State plan rate year described in subparagraph (A) pursuant to this para-

1 graph, a State may retroactively modify a
2 provision of the Medicaid State plan, a
3 waiver of such plan, or a State plan
4 amendment that relates to such rate year
5 and the Secretary may approve such modi-
6 fication.

7 (ii) DEADLINE.—A State may not
8 submit a request for approval of a retro-
9 active modification to a provision of the
10 Medicaid State plan, a waiver of such plan,
11 or a State plan amendment for a Medicaid
12 State plan rate year after the date by
13 which the State is required to submit the
14 independent certified audit for that State
15 plan rate year as required under section
16 1923(j)(2) of the Social Security Act (42
17 U.S.C. 1396r-4(j)(2)).

18 (D) REPORTING.—If a State increases a
19 payment adjustment made to a hospital for a
20 Medicaid State plan rate year pursuant to this
21 paragraph, the State shall include information
22 on such increased payment adjustment as part
23 of the next annual report submitted by the
24 State under section 1923(j)(1) of the Social Se-
25 curity Act (42 U.S.C. 1396r-4(j)(1)).

1 **SEC. 112. ENSURING ACCURATE PAYMENTS TO PHAR-**
 2 **MACIES UNDER MEDICAID.**

3 (a) IN GENERAL.—Section 1927(f) of the Social Se-
 4 curity Act (42 U.S.C. 1396r–8(f)) is amended—

5 (1) in paragraph (1)(A)—

6 (A) by redesignating clause (ii) as clause
 7 (iii); and

8 (B) by striking “and” after the semicolon
 9 at the end of clause (i) and all that precedes it
 10 through “(1)” and inserting the following:

11 “(1) DETERMINING PHARMACY ACTUAL ACQUI-
 12 SITION COSTS.—The Secretary shall conduct a sur-
 13 vey of retail community pharmacy drug prices and
 14 applicable non-retail pharmacy drug prices to deter-
 15 mine national average drug acquisition cost bench-
 16 marks (as such term is defined by the Secretary) as
 17 follows:

18 “(A) USE OF VENDOR.—The Secretary
 19 may contract services for—

20 “(i) with respect to retail community
 21 pharmacies, the determination of retail
 22 survey prices of the national average drug
 23 acquisition cost for covered outpatient
 24 drugs that represent a nationwide average
 25 of consumer purchase prices for such
 26 drugs, net of all discounts, rebates, and

1 other price concessions (to the extent any
2 information with respect to such discounts,
3 rebates, and other price concessions is
4 available) based on a monthly survey of
5 such pharmacies;

6 “(ii) with respect to applicable non-re-
7 tail pharmacies—

8 “(I) the determination of survey
9 prices, separate from the survey prices
10 described in clause (i), of the non-re-
11 tail national average drug acquisition
12 cost for covered outpatient drugs that
13 represent a nationwide average of con-
14 sumer purchase prices for such drugs,
15 net of all discounts, rebates, and other
16 price concessions (to the extent any
17 information with respect to such dis-
18 counts, rebates, and other price con-
19 cessions is available) based on a
20 monthly survey of such pharmacies;
21 and

22 “(II) at the discretion of the Sec-
23 retary, for each type of applicable
24 non-retail pharmacy, the determina-
25 tion of survey prices, separate from

1 the survey prices described in clause
 2 (i) or subclause (I) of this clause, of
 3 the national average drug acquisition
 4 cost for such type of pharmacy for
 5 covered outpatient drugs that rep-
 6 resent a nationwide average of con-
 7 sumer purchase prices for such drugs,
 8 net of all discounts, rebates, and other
 9 price concessions (to the extent any
 10 information with respect to such dis-
 11 counts, rebates, and other price con-
 12 cessions is available) based on a
 13 monthly survey of such pharmacies;
 14 and”;

15 (2) in subparagraph (B) of paragraph (1), by
 16 striking “subparagraph (A)(ii)” and inserting “sub-
 17 paragraph (A)(iii)”;

18 (3) in subparagraph (D) of paragraph (1), by
 19 striking clauses (ii) and (iii) and inserting the fol-
 20 lowing:

21 “(ii) The vendor must update the Sec-
 22 retary no less often than monthly on the
 23 survey prices for covered outpatient drugs.

24 “(iii) The vendor must differentiate,
 25 in collecting and reporting survey data, for

all cost information collected, whether a pharmacy is a retail community pharmacy or an applicable non-retail pharmacy, including whether such pharmacy is an affiliate (as defined in subsection (k)(14)), and, in the case of an applicable non-retail pharmacy, which type of applicable non-retail pharmacy it is using the relevant pharmacy type indicators included in the guidance required by subsection (d)(2) of section 112 of the Bipartisan Health Care Act.”;

(4) by adding at the end of paragraph (1) the following:

“(F) SURVEY REPORTING.—In order to meet the requirement of section 1902(a)(54), a State shall require that any retail community pharmacy or applicable non-retail pharmacy in the State that receives any payment, reimbursement, administrative fee, discount, rebate, or other price concession related to the dispensing of covered outpatient drugs to individuals receiving benefits under this title, regardless of whether such payment, reimbursement, administrative fee, discount, rebate, or other price

1 concession is received from the State or a man-
2 aged care entity or other specified entity (as
3 such terms are defined in section
4 1903(m)(9)(D)) directly or from a pharmacy
5 benefit manager or another entity that has a
6 contract with the State or a managed care enti-
7 ty or other specified entity (as so defined), shall
8 respond to surveys conducted under this para-
9 graph.

10 “(G) SURVEY INFORMATION.—Information
11 on national drug acquisition prices obtained
12 under this paragraph shall be made publicly
13 available in a form and manner to be deter-
14 mined by the Secretary and shall include at
15 least the following:

16 “(i) The monthly response rate to the
17 survey including a list of pharmacies not in
18 compliance with subparagraph (F).

19 “(ii) The sampling methodology and
20 number of pharmacies sampled monthly.

21 “(iii) Information on price concessions
22 to pharmacies, including discounts, re-
23 bates, and other price concessions, to the
24 extent that such information may be pub-

1 licly released and has been collected by the
2 Secretary as part of the survey.

3 “(H) PENALTIES.—

4 “(i) IN GENERAL.—Subject to clauses
5 (ii), (iii), and (iv), the Secretary shall en-
6 force the provisions of this paragraph with
7 respect to a pharmacy through the estab-
8 lishment of civil money penalties applicable
9 to a retail community pharmacy or an ap-
10 plicable non-retail pharmacy.

11 “(ii) BASIS FOR PENALTIES.—The
12 Secretary shall impose a civil money pen-
13 alty established under this subparagraph
14 on a retail community pharmacy or appli-
15 cable non-retail pharmacy if—

16 “(I) the retail pharmacy or appli-
17 cable non-retail pharmacy refuses or
18 otherwise fails to respond to a request
19 for information about prices in con-
20 nection with a survey under this sub-
21 section;

22 “(II) knowingly provides false in-
23 formation in response to such a sur-
24 vey; or

1 “(III) otherwise fails to comply
2 with the requirements established
3 under this paragraph.

4 “(iii) PARAMETERS FOR PEN-
5 ALTIES.—

6 “(I) IN GENERAL.—A civil money
7 penalty established under this sub-
8 paragraph may be assessed with re-
9 spect to each violation, and with re-
10 spect to each non-compliant retail
11 community pharmacy (including a
12 pharmacy that is part of a chain) or
13 non-compliant applicable non-retail
14 pharmacy (including a pharmacy that
15 is part of a chain), in an amount not
16 to exceed \$100,000 for each such vio-
17 lation.

18 “(II) CONSIDERATIONS.—In de-
19 termining the amount of a civil money
20 penalty imposed under this subpara-
21 graph, the Secretary may consider the
22 size, business structure, and type of
23 pharmacy involved, as well as the type
24 of violation and other relevant factors,

1 as determined appropriate by the Sec-
2 retary.

3 “(iv) RULE OF APPLICATION.—The
4 provisions of section 1128A (other than
5 subsections (a) and (b)) shall apply to a
6 civil money penalty under this subpara-
7 graph in the same manner as such provi-
8 sions apply to a civil money penalty or pro-
9 ceeding under section 1128A(a).

10 “(I) LIMITATION ON USE OF APPLICABLE
11 NON-RETAIL PHARMACY PRICING INFORMA-
12 TION.—No State shall use pricing information
13 reported by applicable non-retail pharmacies
14 under subparagraph (A)(ii) to develop or inform
15 payment methodologies for retail community
16 pharmacies.”;

17 (5) in paragraph (2)—

18 (A) in subparagraph (A), by inserting “,
19 including payment rates and methodologies for
20 determining ingredient cost reimbursement
21 under managed care entities or other specified
22 entities (as such terms are defined in section
23 1903(m)(9)(D)),” after “under this title”; and

1 (B) in subparagraph (B), by inserting
2 “and the basis for such dispensing fees” before
3 the semicolon;

4 (6) by redesignating paragraph (4) as para-
5 graph (5);

6 (7) by inserting after paragraph (3) the fol-
7 lowing new paragraph:

8 “(4) OVERSIGHT.—

9 “(A) IN GENERAL.—The Inspector General
10 of the Department of Health and Human Serv-
11 ices shall conduct periodic studies of the survey
12 data reported under this subsection, as appro-
13 priate, including with respect to substantial
14 variations in acquisition costs or other applica-
15 ble costs, as well as with respect to how internal
16 transfer prices and related party transactions
17 may influence the costs reported by pharmacies
18 that are affiliates (as defined in subsection
19 (k)(14)) or are owned by, controlled by, or re-
20 lated under a common ownership structure with
21 a wholesaler, distributor, or other entity that
22 acquires covered outpatient drugs relative to
23 costs reported by pharmacies not affiliated with
24 such entities. The Inspector General shall pro-
25 vide periodic updates to Congress on the results

1 of such studies, as appropriate, in a manner
2 that does not disclose trade secrets or other
3 proprietary information.

4 “(B) APPROPRIATION.—There is appro-
5 priated to the Inspector General of the Depart-
6 ment of Health and Human Services, out of
7 any money in the Treasury not otherwise ap-
8 propriated, \$5,000,000 for fiscal year 2025, to
9 remain available until expended, to carry out
10 this paragraph.”; and

11 (8) in paragraph (5), as so redesignated—

12 (A) by inserting “, and \$9,000,000 for fis-
13 cal year 2025 and each fiscal year thereafter,”
14 after “2010”; and

15 (B) by inserting “Funds appropriated
16 under this paragraph for fiscal year 2025 and
17 any subsequent fiscal year shall remain avail-
18 able until expended.” after the period.

19 (b) DEFINITIONS.—Section 1927(k) of the Social Se-
20 curity Act (42 U.S.C. 1396r–8(k)) is amended—

21 (1) in the matter preceding paragraph (1), by
22 striking “In the section” and inserting “In this sec-
23 tion”; and

24 (2) by adding at the end the following new
25 paragraphs:

1 “(12) APPLICABLE NON-RETAIL PHARMACY.—

2 The term ‘applicable non-retail pharmacy’ means a
 3 pharmacy that is licensed as a pharmacy by the
 4 State and that is not a retail community pharmacy,
 5 including a pharmacy that dispenses prescription
 6 medications to patients primarily through mail and
 7 specialty pharmacies. Such term does not include
 8 nursing home pharmacies, long-term care facility
 9 pharmacies, hospital pharmacies, clinics, charitable
 10 or not-for-profit pharmacies, government phar-
 11 macies, or low dispensing pharmacies (as defined by
 12 the Secretary).

13 “(13) AFFILIATE.—The term ‘affiliate’ means
 14 any entity that is owned by, controlled by, or related
 15 under a common ownership structure with a phar-
 16 macy benefit manager or a managed care entity or
 17 other specified entity (as such terms are defined in
 18 section 1903(m)(9)(D)).”.

19 (c) EFFECTIVE DATE.—

20 (1) IN GENERAL.—Subject to paragraph (2),
 21 the amendments made by this section shall take ef-
 22 fect on the first day of the first quarter that begins
 23 on or after the date that is 6 months after the date
 24 of enactment of this Act.

1 (2) DELAYED APPLICATION TO APPLICABLE
2 NON-RETAIL PHARMACIES.—The pharmacy survey
3 requirements established by the amendments to sec-
4 tion 1927(f) of the Social Security Act (42 U.S.C.
5 1396r–8(f)) made by this section shall apply to re-
6 tail community pharmacies beginning on the effec-
7 tive date described in paragraph (1), but shall not
8 apply to applicable non-retail pharmacies until the
9 first day of the first quarter that begins on or after
10 the date that is 18 months after the date of enact-
11 ment of this Act.

12 (d) IDENTIFICATION OF APPLICABLE NON-RETAIL
13 PHARMACIES.—

14 (1) IN GENERAL.—Not later than January 1,
15 2026, the Secretary of Health and Human Services
16 shall, in consultation with stakeholders as appro-
17 priate, publish guidance specifying pharmacies that
18 meet the definition of applicable non-retail phar-
19 macies (as such term is defined in subsection
20 (k)(12) of section 1927 of the Social Security Act
21 (42 U.S.C. 1396r–8), as added by subsection (b)),
22 and that will be subject to the survey requirements
23 under subsection (f)(1) of such section, as amended
24 by subsection (a).

1 (2) INCLUSION OF PHARMACY TYPE INDICA-
2 TORS.—The guidance published under paragraph (1)
3 shall include pharmacy type indicators to distinguish
4 between different types of applicable non-retail phar-
5 macies, such as pharmacies that dispense prescrip-
6 tions primarily through the mail and pharmacies
7 that dispense prescriptions that require special han-
8 dling or distribution. An applicable non-retail phar-
9 macy may be identified through multiple pharmacy
10 type indicators.

11 (e) IMPLEMENTATION.—

12 (1) IN GENERAL.—Notwithstanding any other
13 provision of law, the Secretary of Health and
14 Human Services may implement the amendments
15 made by this section by program instruction or oth-
16 erwise.

17 (2) NONAPPLICATION OF ADMINISTRATIVE PRO-
18 CEDURE ACT.—Implementation of the amendments
19 made by this section shall be exempt from the re-
20 quirements of section 553 of title 5, United States
21 Code.

22 (f) NONAPPLICATION OF PAPERWORK REDUCTION
23 ACT.—Chapter 35 of title 44, United States Code, shall
24 not apply to any data collection undertaken by the Sec-
25 retary of Health and Human Services under section

1 1927(f) of the Social Security Act (42 U.S.C. 1396r–8(f)),
 2 as amended by this section.

3 **SEC. 113. PREVENTING THE USE OF ABUSIVE SPREAD PRIC-**
 4 **ING IN MEDICAID.**

5 (a) IN GENERAL.—Section 1927 of the Social Secu-
 6 rity Act (42 U.S.C. 1396r–8) is amended—

7 (1) in subsection (e), by adding at the end the
 8 following new paragraph:

9 “(6) TRANSPARENT PRESCRIPTION DRUG PASS-
 10 THROUGH PRICING REQUIRED.—

11 “(A) IN GENERAL.—A contract between
 12 the State and a pharmacy benefit manager (re-
 13 ferred to in this paragraph as a ‘PBM’), or a
 14 contract between the State and a managed care
 15 entity or other specified entity (as such terms
 16 are defined in section 1903(m)(9)(D) and col-
 17 lectively referred to in this paragraph as the
 18 ‘entity’) that includes provisions making the en-
 19 tity responsible for coverage of covered out-
 20 patient drugs dispensed to individuals enrolled
 21 with the entity, shall require that payment for
 22 such drugs and related administrative services
 23 (as applicable), including payments made by a
 24 PBM on behalf of the State or entity, is based

1 on a transparent prescription drug pass-
2 through pricing model under which—

3 “(i) any payment made by the entity
4 or the PBM (as applicable) for such a
5 drug—

6 “(I) is limited to—

7 “(aa) ingredient cost; and

8 “(bb) a professional dis-
9 pensing fee that is not less than
10 the professional dispensing fee
11 that the State would pay if the
12 State were making the payment
13 directly in accordance with the
14 State plan;

15 “(II) is passed through in its en-
16 tirety (except as reduced under Fed-
17 eral or State laws and regulations in
18 response to instances of waste, fraud,
19 or abuse) by the entity or PBM to the
20 pharmacy or provider that dispenses
21 the drug; and

22 “(III) is made in a manner that
23 is consistent with sections 447.502,
24 447.512, 447.514, and 447.518 of
25 title 42, Code of Federal Regulations

1 (or any successor regulation) as if
2 such requirements applied directly to
3 the entity or the PBM, except that
4 any payment by the entity or the
5 PBM for the ingredient cost of such
6 drug purchased by a covered entity
7 (as defined in subsection (a)(5)(B))
8 may exceed the actual acquisition cost
9 (as defined in 447.502 of title 42,
10 Code of Federal Regulations, or any
11 successor regulation) for such drug
12 if—

13 “(aa) such drug was subject
14 to an agreement under section
15 340B of the Public Health Serv-
16 ice Act;

17 “(bb) such payment for the
18 ingredient cost of such drug does
19 not exceed the maximum pay-
20 ment that would have been made
21 by the entity or the PBM for the
22 ingredient cost of such drug if
23 such drug had not been pur-
24 chased by such covered entity;
25 and

1 “(cc) such covered entity re-
2 ports to the Secretary (in a form
3 and manner specified by the Sec-
4 retary), on an annual basis and
5 with respect to payments for the
6 ingredient costs of such drugs so
7 purchased by such covered entity
8 that are in excess of the actual
9 acquisition costs for such drugs,
10 the aggregate amount of such ex-
11 cess;

12 “(ii) payment to the entity or the
13 PBM (as applicable) for administrative
14 services performed by the entity or PBM is
15 limited to an administrative fee that re-
16 flects the fair market value (as defined by
17 the Secretary) of such services;

18 “(iii) the entity or the PBM (as appli-
19 cable) makes available to the State, and
20 the Secretary upon request in a form and
21 manner specified by the Secretary, all costs
22 and payments related to covered outpatient
23 drugs and accompanying administrative
24 services (as described in clause (ii)) in-
25 curred, received, or made by the entity or

1 the PBM, broken down (as specified by the
2 Secretary), to the extent such costs and
3 payments are attributable to an individual
4 covered outpatient drug, by each such
5 drug, including any ingredient costs, pro-
6 fessional dispensing fees, administrative
7 fees (as described in clause (ii)), post-sale
8 and post-invoice fees, discounts, or related
9 adjustments such as direct and indirect re-
10 muneration fees, and any and all other re-
11 muneration, as defined by the Secretary;
12 and

13 “(iv) any form of spread pricing
14 whereby any amount charged or claimed by
15 the entity or the PBM (as applicable) that
16 exceeds the amount paid to the pharmacies
17 or providers on behalf of the State or enti-
18 ty, including any post-sale or post-invoice
19 fees, discounts, or related adjustments
20 such as direct and indirect remuneration
21 fees or assessments, as defined by the Sec-
22 retary, (after allowing for an administra-
23 tive fee as described in clause (ii)) is not
24 allowable for purposes of claiming Federal
25 matching payments under this title.

1 “(B) PUBLICATION OF INFORMATION.—

2 The Secretary shall publish, not less frequently
3 than on an annual basis and in a manner that
4 does not disclose the identity of a particular
5 covered entity or organization, information re-
6 ceived by the Secretary pursuant to subpara-
7 graph (A)(iii)(III) that is broken out by State
8 and by each of the following categories of cov-
9 ered entity within each such State:

10 “(i) Covered entities described in sub-
11 paragraph (A) of section 340B(a)(4) of the
12 Public Health Service Act.

13 “(ii) Covered entities described in sub-
14 paragraphs (B) through (K) of such sec-
15 tion.

16 “(iii) Covered entities described in
17 subparagraph (L) of such section.

18 “(iv) Covered entities described in
19 subparagraph (M) of such section.

20 “(v) Covered entities described in sub-
21 paragraph (N) of such section.

22 “(vi) Covered entities described in
23 subparagraph (O) of such section.”; and

(2) in subsection (k), as previously amended by this title, by adding at the end the following new paragraph:

“(14) PHARMACY BENEFIT MANAGER.—The term ‘pharmacy benefit manager’ means any person or entity that, either directly or through an intermediary, acts as a price negotiator or group purchaser on behalf of a State, managed care entity (as defined in section 1903(m)(9)(D)), or other specified entity (as so defined), or manages the prescription drug benefits provided by a State, managed care entity, or other specified entity, including the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the managing of appeals or grievances related to the prescription drug benefits, contracting with pharmacies, controlling the cost of covered outpatient drugs, or the provision of services related thereto. Such term includes any person or entity that acts as a price negotiator (with regard to payment amounts to pharmacies and providers for a covered outpatient drug or the net cost of the drug) or group purchaser on behalf of a State, managed care entity, or other specified entity or that carries out 1 or more of the

1 other activities described in the preceding sentence,
 2 irrespective of whether such person or entity calls
 3 itself a pharmacy benefit manager.”.

4 (b) CONFORMING AMENDMENTS.—Section 1903(m)
 5 of such Act (42 U.S.C. 1396b(m)) is amended—

6 (1) in paragraph (2)(A)(xiii)—

7 (A) by striking “and (III)” and inserting
 8 “(III)”;

9 (B) by inserting before the period at the
 10 end the following: “, and (IV) if the contract in-
 11 cludes provisions making the entity responsible
 12 for coverage of covered outpatient drugs, the
 13 entity shall comply with the requirements of
 14 section 1927(e)(6)”;

15 (C) by moving the margin 2 ems to the
 16 left; and

17 (2) by adding at the end the following new
 18 paragraph:

19 “(10) No payment shall be made under this
 20 title to a State with respect to expenditures incurred
 21 by the State for payment for services provided by an
 22 other specified entity (as defined in paragraph
 23 (9)(D)(iii)) unless such services are provided in ac-
 24 cordance with a contract between the State and such

1 entity which satisfies the requirements of paragraph
2 (2)(A)(xiii).”.

3 (c) EFFECTIVE DATE.—The amendments made by
4 this section shall apply to contracts between States and
5 managed care entities, other specified entities, or phar-
6 macy benefit managers that have an effective date begin-
7 ning on or after the date that is 18 months after the date
8 of enactment of this Act.

9 (d) IMPLEMENTATION.—

10 (1) IN GENERAL.—Notwithstanding any other
11 provision of law, the Secretary of Health and
12 Human Services may implement the amendments
13 made by this section by program instruction or oth-
14 erwise.

15 (2) NONAPPLICATION OF ADMINISTRATIVE PRO-
16 CEDURE ACT.—Implementation of the amendments
17 made by this section shall be exempt from the re-
18 quirements of section 553 of title 5, United States
19 Code.

20 (e) NONAPPLICATION OF PAPERWORK REDUCTION
21 ACT.—Chapter 35 of title 44, United States Code, shall
22 not apply to any data collection undertaken by the Sec-
23 retary of Health and Human Services under section
24 1927(e) of the Social Security Act (42 U.S.C. 1396r-
25 8(e)), as amended by this section.

TITLE II—MEDICARE

SEC. 201. EXTENSION OF INCREASED INPATIENT HOSPITAL PAYMENT ADJUSTMENT FOR CERTAIN LOW- VOLUME HOSPITALS.

(a) IN GENERAL.—Section 1886(d)(12) of the Social Security Act (42 U.S.C. 1395ww(d)(12)) is amended—

(1) in subparagraph (B), in the matter preceding clause (i), by striking “fiscal year 2025 beginning on April 1, 2025, and ending on September 30, 2025, and in fiscal year 2026” and inserting “fiscal year 2026 beginning on January 1, 2026, and ending on September 30, 2026, and in fiscal year 2027”;

(2) in subparagraph (C)(i)—

(A) in the matter preceding subclause (I), by striking “through 2024 and the portion of fiscal year 2025 beginning on October 1, 2024, and ending on March 31, 2025” and inserting “through 2025 and the portion of fiscal year 2026 beginning on October 1, 2025, and ending on December 31, 2025”;

(B) in subclause (III), by striking “through 2024 and the portion of fiscal year 2025 beginning on October 1, 2024, and ending on March 31, 2025” and inserting “through

1 2025 and the portion of fiscal year 2026 begin-
 2 ning on October 1, 2025, and ending on De-
 3 cember 31, 2025”; and

4 (C) in subclause (IV), by striking “fiscal
 5 year 2025 beginning on April 1, 2025, and end-
 6 ing on September 30, 2025, and fiscal year
 7 2026” and inserting “fiscal year 2026 begin-
 8 ning on January 1, 2026, and ending on Sep-
 9 tember 30, 2026, and fiscal year 2027”; and
 10 (3) in subparagraph (D)—

11 (A) in the matter preceding clause (i), by
 12 striking “through 2024 or during the portion of
 13 fiscal year 2025 beginning on October 1, 2024,
 14 and ending on March 31, 2025” and inserting
 15 “through 2025 or during the portion of fiscal
 16 year 2026 beginning on October 1, 2025, and
 17 ending on December 31, 2025”; and

18 (B) in clause (ii), by striking “through
 19 2024 and the portion of fiscal year 2025 begin-
 20 ning on October 1, 2024, and ending on March
 21 31, 2025” and inserting “through 2025 and the
 22 portion of fiscal year 2026 beginning on Octo-
 23 ber 1, 2025, and ending on December 31,
 24 2025”.

1 (b) IMPLEMENTATION.—Notwithstanding any other
 2 provision of law, the Secretary of Health and Human
 3 Services may implement the amendments made by this
 4 section by program instruction or otherwise.

5 **SEC. 202. EXTENSION OF THE MEDICARE-DEPENDENT HOS-**
 6 **PITAL (MDH) PROGRAM.**

7 (a) IN GENERAL.—Section 1886(d)(5)(G) of the So-
 8 cial Security Act (42 U.S.C. 1395ww(d)(5)(G)) is amend-
 9 ed—

10 (1) in clause (i), by striking “April 1, 2025”
 11 and inserting “January 1, 2026”; and

12 (2) in clause (ii)(II), by striking “April 1,
 13 2025” and inserting “January 1, 2026”.

14 (b) CONFORMING AMENDMENTS.—

15 (1) IN GENERAL.—Section 1886(b)(3)(D) of
 16 the Social Security Act (42 U.S.C.
 17 1395ww(b)(3)(D)) is amended—

18 (A) in the matter preceding clause (i), by
 19 striking “April 1, 2025” and inserting “Janu-
 20 ary 1, 2026”; and

21 (B) in clause (iv), by striking “through fis-
 22 cal year 2024 and the portion of fiscal year
 23 2025 beginning on October 1, 2024, and ending
 24 on March 31, 2025” and inserting “through fis-
 25 cal year 2025 and the portion of fiscal year

1 2026 beginning on October 1, 2025, and ending
2 on December 31, 2025”.

3 (2) PERMITTING HOSPITALS TO DECLINE RE-
4 CLASSIFICATION.—Section 13501(e)(2) of the Omni-
5 bus Budget Reconciliation Act of 1993 (42 U.S.C.
6 1395ww note) is amended by striking “through fis-
7 cal year 2024, or the portion of fiscal year 2025 be-
8 ginning on October 1, 2024, and ending on March
9 31, 2025” and inserting “through fiscal year 2025,
10 or the portion of fiscal year 2026 beginning on Octo-
11 ber 1, 2025, and ending on December 31, 2025”.

12 **SEC. 203. EXTENSION OF ADD-ON PAYMENTS FOR AMBU-**
13 **LANCE SERVICES.**

14 Section 1834(l) of the Social Security Act (42 U.S.C.
15 1395m(l)) is amended—

16 (1) in paragraph (12)(A), by striking “April 1,
17 2025” and inserting “January 1, 2027”; and

18 (2) in paragraph (13), by striking “April 1,
19 2025” each place it appears and inserting “January
20 1, 2027” in each such place.

21 **SEC. 204. EXTENDING INCENTIVE PAYMENTS FOR PARTICI-**
22 **PATION IN ELIGIBLE ALTERNATIVE PAYMENT**
23 **MODELS.**

24 (a) IN GENERAL.—Section 1833(z) of the Social Se-
25 curity Act (42 U.S.C. 1395l(z)) is amended—

1 (1) in paragraph (1)(A)—

2 (A) by striking “with 2026” and inserting
3 “with 2027”; and

4 (B) by inserting “, or, with respect to
5 2027, 3.53 percent” after “1.88 percent”;

6 (2) in paragraph (2)—

7 (A) in subparagraph (B)—

8 (i) in the heading, by striking “2026”
9 and inserting “2027”; and

10 (ii) in the matter preceding clause (i),
11 by striking “2026” and inserting “2027”;

12 (B) in subparagraph (C)—

13 (i) in the heading, by striking “2027”
14 and inserting “2028”; and

15 (ii) in the matter preceding clause (i),
16 by striking “2027” and inserting “2028”;
17 and

18 (C) in subparagraph (D), by striking “and
19 2026” and inserting “2026, and 2027”; and

20 (3) in paragraph (4)(B), by inserting “or, with
21 respect to 2027, 3.53 percent” after “1.88 percent”.

22 (b) CONFORMING AMENDMENTS.—Section
23 1848(q)(1)(C)(iii) of the Social Security Act (42 U.S.C.
24 1395w–4(q)(1)(C)(iii)) is amended—

1 (1) in subclause (II), by striking “2026” and
 2 inserting “2027”; and

3 (2) in subclause (III), by striking “2027” and
 4 inserting “2028”.

5 **SEC. 205. TEMPORARY PAYMENT INCREASE UNDER THE**
 6 **MEDICARE PHYSICIAN FEE SCHEDULE TO AC-**
 7 **COUNT FOR EXCEPTIONAL CIRCUMSTANCES.**

8 (a) IN GENERAL.—Section 1848(t)(1) of the Social
 9 Security Act (42 U.S.C. 1395w–4(t)(1)) is amended—

10 (1) in subparagraph (D), by striking “and” at
 11 the end;

12 (2) in subparagraph (E), by striking the period
 13 at the end and inserting “; and”; and

14 (3) by adding at the end the following new sub-
 15 paragraph:

16 “(F) such services furnished on or after
 17 March 15, 2025, and before January 1, 2026,
 18 by 3.5375 percent.”.

19 (b) CONFORMING AMENDMENT.—Section
 20 1848(c)(2)(B)(iv)(V) is amended by striking “or 2024”
 21 and inserting “2024, or 2025”.

22 **SEC. 206. EXTENSION OF FUNDING FOR QUALITY MEASURE**
 23 **ENDORSEMENT, INPUT, AND SELECTION.**

24 Section 1890(d)(2) of the Social Security Act (42
 25 U.S.C. 1395aaa(d)(2)) is amended—

1 (1) in the first sentence—

2 (A) by striking “\$11,030,000” and insert-
3 ing “\$14,000,000”; and

4 (B) by striking “March 31, 2025” and in-
5 serting “December 31, 2025”; and

6 (2) in the third sentence, by striking “March
7 31, 2025” and inserting “December 31, 2025”.

8 **SEC. 207. EXTENSION OF FUNDING OUTREACH AND ASSIST-**
9 **ANCE FOR LOW-INCOME PROGRAMS.**

10 (a) STATE HEALTH INSURANCE ASSISTANCE PRO-
11 GRAMS.—Subsection (a)(1)(B) of section 119 of the Medi-
12 care Improvements for Patients and Providers Act of 2008
13 (42 U.S.C. 1395b–3 note) is amended—

14 (1) in clause (xiii), by striking “and” at the
15 end;

16 (2) in clause (xiv), by striking the period and
17 inserting “; and”; and

18 (3) by inserting after clause (xiv) the following
19 new clause:

20 “(xv) for the period beginning on
21 April 1, 2025, and ending on December
22 31, 2026, \$26,250,000.”.

23 (b) AREA AGENCIES ON AGING.—Subsection
24 (b)(1)(B) of such section 119 is amended—

1 (1) in clause (xiii), by striking “and” at the
2 end;

3 (2) in clause (xiv), by striking the period and
4 inserting “; and”; and

5 (3) by inserting after clause (xiv) the following
6 new clause:

7 “(xv) for the period beginning on
8 April 1, 2025, and ending on December
9 31, 2026, \$26,250,000.”.

10 (c) AGING AND DISABILITY RESOURCE CENTERS.—

11 Subsection (c)(1)(B) of such section 119 is amended—

12 (1) in clause (xiii), by striking “and” at the
13 end;

14 (2) in clause (xiv), by striking the period and
15 inserting “; and”; and

16 (3) by inserting after clause (xiv) the following
17 new clause:

18 “(xv) for the period beginning on
19 April 1, 2025, and ending on December
20 31, 2026, \$7,750,000.”.

21 (d) COORDINATION OF EFFORTS TO INFORM OLDER

22 AMERICANS ABOUT BENEFITS AVAILABLE UNDER FED-

23 ERAL AND STATE PROGRAMS.—Subsection (d)(2) of such

24 section 119 is amended—

1 (1) in clause (xiii), by striking “and” at the
2 end;

3 (2) in clause (xiv), by striking the period and
4 inserting “; and”; and

5 (3) by inserting after clause (xiv) the following
6 new clause:

7 “(xv) for the period beginning on
8 April 1, 2025, and ending on December
9 31, 2026, \$26,250,000.”.

10 **SEC. 208. EXTENSION OF THE WORK GEOGRAPHIC INDEX**
11 **FLOOR.**

12 Section 1848(e)(1)(E) of the Social Security Act (42
13 U.S.C. 1395w-4(e)(1)(E)) is amended by striking “April
14 1, 2025” and inserting “January 1, 2026”.

15 **SEC. 209. EXTENSION OF CERTAIN TELEHEALTH FLEXIBILI-**
16 **TIES.**

17 (a) REMOVING GEOGRAPHIC REQUIREMENTS AND
18 EXPANDING ORIGINATING SITES FOR TELEHEALTH
19 SERVICES.—Section 1834(m) of the Social Security Act
20 (42 U.S.C. 1395m(m)) is amended—

21 (1) in paragraph (2)(B)(iii), by striking “end-
22 ing March 31, 2025” and inserting “ending Decem-
23 ber 31, 2026”; and

1 (2) in paragraph (4)(C)(iii), by striking “ending
2 on March 31, 2025” and inserting “ending on De-
3 cember 31, 2026”.

4 (b) EXPANDING PRACTITIONERS ELIGIBLE TO FUR-
5 NISH TELEHEALTH SERVICES.—Section 1834(m)(4)(E)
6 of the Social Security Act (42 U.S.C. 1395m(m)(4)(E))
7 is amended by striking “ending on March 31, 2025” and
8 inserting “ending on December 31, 2026”.

9 (c) EXTENDING TELEHEALTH SERVICES FOR FED-
10 ERALLY QUALIFIED HEALTH CENTERS AND RURAL
11 HEALTH CLINICS.—Section 1834(m)(8) of the Social Se-
12 curity Act (42 U.S.C. 1395m(m)(8)) is amended—

13 (1) in subparagraph (A), by striking “ending on
14 March 31, 2025” and inserting “ending on Decem-
15 ber 31, 2026”;

16 (2) in subparagraph (B)—

17 (A) in the subparagraph heading, by in-
18 serting “BEFORE APRIL 1, 2025” after “RULE”;

19 (B) in clause (i), by striking “during the
20 periods for which subparagraph (A) applies”
21 and inserting “before April 1, 2025”; and

22 (C) in clause (ii), by inserting “furnished
23 to an eligible telehealth individual before April
24 1, 2025” after “telehealth services”; and

(3) by adding at the end the following new subparagraph:

“(C) PAYMENT RULE FOR PORTION OF 2025 AND 2026.—

“(i) IN GENERAL.—A telehealth service furnished to an eligible telehealth individual by a Federally qualified health center or rural health clinic on or after April 1, 2025, and before January 1, 2027, shall be paid as a Federally qualified health center service or rural health clinic service (as applicable) under the prospective payment system established under section 1834(o) or the methodology for all-inclusive rates established under section 1833(a)(3), respectively.

“(ii) TREATMENT OF COSTS.—Costs associated with the furnishing of telehealth services by a Federally qualified health center or rural health clinic on or after April 1, 2025, and before January 1, 2027, shall be considered allowable costs for purposes of the prospective payment system established under section 1834(o) and the methodology for all-inclusive rates

1 established under section 1833(a)(3), as
 2 applicable.

3 “(iii) REQUIRING MODIFIERS.—Not
 4 later than July 1, 2025, the Secretary
 5 shall establish requirements to include 1 or
 6 more codes or modifiers, as determined ap-
 7 propriate by the Secretary, in the case of
 8 claims for telehealth services furnished to
 9 an eligible telehealth individual by a Feder-
 10 ally qualified health center or rural health
 11 clinic.”.

12 (d) DELAYING THE IN-PERSON REQUIREMENTS
 13 UNDER MEDICARE FOR MENTAL HEALTH SERVICES
 14 FURNISHED THROUGH TELEHEALTH AND TELE-
 15 COMMUNICATIONS TECHNOLOGY.—

16 (1) DELAY IN REQUIREMENTS FOR MENTAL
 17 HEALTH SERVICES FURNISHED THROUGH TELE-
 18 HEALTH.—Section 1834(m)(7)(B)(i) of the Social
 19 Security Act (42 U.S.C. 1395m(m)(7)(B)(i)) is
 20 amended, in the matter preceding subclause (I), by
 21 striking “April 1, 2025” and inserting “January 1,
 22 2027”.

23 (2) MENTAL HEALTH VISITS FURNISHED BY
 24 RURAL HEALTH CLINICS.—Section 1834(y)(2) of the
 25 Social Security Act (42 U.S.C. 1395m(y)(2)) is

1 amended by striking “April 1, 2025” and inserting
 2 “January 1, 2027”.

3 (3) MENTAL HEALTH VISITS FURNISHED BY
 4 FEDERALLY QUALIFIED HEALTH CENTERS.—Section
 5 1834(o)(4)(B) of the Social Security Act (42 U.S.C.
 6 1395m(o)(4)(B)) is amended by striking “April 1,
 7 2025” and inserting “January 1, 2027”.

8 (e) ALLOWING FOR THE FURNISHING OF AUDIO-
 9 ONLY TELEHEALTH SERVICES.—Section 1834(m)(9) of
 10 the Social Security Act (42 U.S.C. 1395m(m)(9)) is
 11 amended by striking “ending on March 31, 2025” and in-
 12 serting “ending on December 31, 2026”.

13 (f) EXTENDING USE OF TELEHEALTH TO CONDUCT
 14 FACE-TO-FACE ENCOUNTER PRIOR TO RECERTIFICATION
 15 OF ELIGIBILITY FOR HOSPICE CARE.—Section
 16 1814(a)(7)(D)(i)(II) of the Social Security Act (42 U.S.C.
 17 1395f(a)(7)(D)(i)(II)) is amended—

18 (1) by striking “ending on March 31, 2025”
 19 and inserting “ending on December 31, 2026”; and

20 (2) by inserting “, except that this subclause
 21 shall not apply in the case of such an encounter with
 22 an individual occurring on or after April 1, 2025, if
 23 such individual is located in an area that is subject
 24 to a moratorium on the enrollment of hospice pro-
 25 grams under this title pursuant to section

1 1866(j)(7), if such individual is receiving hospice
 2 care from a provider that is subject to enhanced
 3 oversight under this title pursuant to section
 4 1866(j)(3), or if such encounter is performed by a
 5 hospice physician or nurse practitioner who is not
 6 enrolled under section 1866(j) and is not an opt-out
 7 physician or practitioner (as defined in section
 8 1802(b)(6)(D))” before the semicolon.

9 (g) **REQUIRING MODIFIERS FOR TELEHEALTH SERV-**
 10 **ICES IN CERTAIN INSTANCES.**—Section 1834(m) of the
 11 Social Security Act (42 U.S.C. 1395m(m)) is amended by
 12 adding at the end the following new paragraph:

13 “(10) **REQUIRED USE OF MODIFIERS IN CER-**
 14 **TAIN INSTANCES.**—Not later than January 1, 2026,
 15 the Secretary shall establish requirements to include
 16 1 or more codes or modifiers, as determined appro-
 17 priate by the Secretary, in the case of—

18 “(A) claims for telehealth services under
 19 this subsection that are furnished through a
 20 telehealth virtual platform—

21 “(i) by a physician or practitioner
 22 that contracts with an entity that owns
 23 such virtual platform; or

1 “(ii) for which a physician or practi-
 2 tioner has a payment arrangement with an
 3 entity for use of such virtual platform; and
 4 “(B) claims for telehealth services under
 5 this subsection that are furnished incident to a
 6 physician’s or practitioner’s professional serv-
 7 ice.”.

8 (h) PROGRAM INSTRUCTION AUTHORITY.—The Sec-
 9 retary of Health and Human Services may implement the
 10 amendments made by this section through program in-
 11 struction or otherwise.

12 **SEC. 210. REQUIRING MODIFIER FOR USE OF TELEHEALTH**
 13 **TO CONDUCT FACE-TO-FACE ENCOUNTER**
 14 **PRIOR TO RECERTIFICATION OF ELIGIBILITY**
 15 **FOR HOSPICE CARE.**

16 Section 1814(a)(7)(D)(i)(II) of the Social Security
 17 Act (42 U.S.C. 1395f(a)(7)(D)(i)(II)), as amended by sec-
 18 tion 209(f), is further amended by inserting “, but only
 19 if, in the case of such an encounter occurring on or after
 20 January 1, 2026, any hospice claim includes 1 or more
 21 modifiers or codes (as specified by the Secretary) to indi-
 22 cate that such encounter was conducted via telehealth”
 23 after “as determined appropriate by the Secretary”.

1 **SEC. 211. EXTENDING ACUTE HOSPITAL CARE AT HOME**
 2 **WAIVER FLEXIBILITIES.**

3 Section 1866G of the Social Security Act (42 U.S.C.
 4 1395cc-7) is amended—

5 (1) in the section heading, by inserting “**THE**
 6 **THOMAS R. CARPER, TIM SCOTT, BRAD R.**
 7 **WENSTRUP, D.P.M., AND EARL BLUMENAUER**”
 8 after “**EXTENSION OF**”;

9 (2) in subsection (a)—

10 (A) in paragraph (1)—

11 (i) by striking “March 31, 2025” and
 12 inserting “December 31, 2029”; and

13 (ii) by striking “in the Acute Hospital
 14 Care at Home initiative of the Secretary”
 15 and inserting “in the Thomas R. Carper,
 16 Tim Scott, Brad R. Wenstrup, D.P.M.,
 17 and Earl Blumenauer Acute Hospital Care
 18 at Home initiative of the Secretary (in this
 19 section referred to as the ‘Acute Hospital
 20 Care at Home initiative’)”;

21 (B) in paragraph (2), by striking “of the
 22 Secretary”; and

23 (C) in paragraph (3)(E), by adding at the
 24 end the following new flush sentence:

25 “The Secretary may require that such data and
 26 information be submitted through a hospital’s

cost report, through such survey instruments as the Secretary may develop, through medical record information, or through such other means as the Secretary determines appropriate.”;

(3) in subsection (b)—

(A) in the subsection heading, by striking “STUDY” and inserting “INITIAL STUDY”;

(B) in paragraph (1)(A), by striking “of the Secretary”; and

(C) in paragraph (3), by inserting “or subsection (c)” before the period at the end;

(4) by redesignating subsections (c) and (d) as subsections (d) and (e), respectively; and

(5) by inserting after subsection (b) the following new subsection:

“(c) SUBSEQUENT STUDY AND REPORT.—

“(1) IN GENERAL.—Not later than September 30, 2028, the Secretary shall conduct a study to—

“(A) analyze, to the extent practicable, the criteria established by hospitals under the Acute Hospital Care at Home initiative to determine which individuals may be furnished services under such initiative; and

1 “(B) analyze and compare (both within
2 and between hospitals participating in the ini-
3 tiative, and relative to comparable hospitals
4 that do not participate in the initiative, for rel-
5 evant parameters such as diagnosis-related
6 groups)—

7 “(i) quality of care furnished to indi-
8 viduals with similar conditions and charac-
9 teristics in the inpatient setting and
10 through the Acute Hospital Care at Home
11 initiative, including health outcomes, hos-
12 pital readmission rates (including readmis-
13 sions both within and beyond 30 days post-
14 discharge), hospital mortality rates, length
15 of stay, infection rates, composition of care
16 team (including the types of labor used,
17 such as contracted labor), the ratio of
18 nursing staff, transfers from the hospital
19 to the home, transfers from the home to
20 the hospital (including the timing, fre-
21 quency, and causes of such transfers),
22 transfers and discharges to post-acute care
23 settings (including the timing, frequency,
24 and causes of such transfers and dis-

1 charges), and patient and caregiver experi-
2 ence of care;

3 “(ii) clinical conditions treated and di-
4 agnosis-related groups of discharges from
5 inpatient settings relative to discharges
6 from the Acute Hospital Care at Home ini-
7 tiative;

8 “(iii) costs incurred by the hospital
9 for furnishing care in inpatient settings
10 relative to costs incurred by the hospital
11 for furnishing care through the Acute Hos-
12 pital Care at Home initiative, including
13 costs relating to staffing, equipment, food,
14 prescriptions, and other services, as deter-
15 mined by the Secretary;

16 “(iv) the quantity, mix, and intensity
17 of services (such as in-person visits and
18 virtual contacts with patients and the in-
19 tensity of such services) furnished in inpa-
20 tient settings relative to the Acute Hospital
21 Care at Home initiative, and, to the extent
22 practicable, the nature and extent of family
23 or caregiver involvement;

24 “(v) socioeconomic information on in-
25 dividuals treated in comparable inpatient

1 settings relative to the initiative, including
2 racial and ethnic data, income, housing,
3 geographic proximity to the brick-and-mor-
4 tar facility and whether such individuals
5 are dually eligible for benefits under this
6 title and title XIX; and

7 “(vi) the quality of care, outcomes,
8 costs, quantity and intensity of services,
9 and other relevant metrics between individ-
10 uals who entered into the Acute Hospital
11 Care at Home initiative directly from an
12 emergency department compared with indi-
13 viduals who entered into the Acute Hos-
14 pital Care at Home initiative directly from
15 an existing inpatient stay in a hospital.

16 “(2) SELECTION BIAS.—In conducting the
17 study under paragraph (1), the Secretary shall, to
18 the extent practicable, analyze and compare individ-
19 uals who participate and do not participate in the
20 initiative controlling for selection bias or other fac-
21 tors that may impact the reliability of data.

22 “(3) REPORT.—Not later than September 30,
23 2028, the Secretary of Health and Human Services
24 shall post on a website of the Centers for Medicare

1 & Medicaid Services a report on the study conducted
2 under paragraph (1).

3 “(4) FUNDING.—In addition to amounts other-
4 wise available, there is appropriated to the Centers
5 for Medicare & Medicaid Services Program Manage-
6 ment Account for fiscal year 2026, out of any
7 amounts in the Treasury not otherwise appropriated,
8 \$6,000,000, respectively, to remain available until
9 expended, for purposes of carrying out this section.”.

10 **SEC. 212. ENHANCING CERTAIN PROGRAM INTEGRITY RE-**
11 **QUIREMENTS FOR DME UNDER MEDICARE.**

12 (a) DURABLE MEDICAL EQUIPMENT.—

13 (1) IN GENERAL.—Section 1834(a) of the So-
14 cial Security Act (42 U.S.C. 1395m(a)) is amended
15 by adding at the end the following new paragraph:

16 “(23) MASTER LIST INCLUSION AND CLAIM RE-
17 VIEW FOR CERTAIN ITEMS.—

18 “(A) MASTER LIST INCLUSION.—Begin-
19 ning January 1, 2028, for purposes of the Mas-
20 ter List described in section 414.234(b) of title
21 42, Code of Federal Regulations (or any suc-
22 cessor regulation), an item for which payment
23 may be made under this subsection shall be
24 treated as having aberrant billing patterns (as
25 such term is used for purposes of such section)

1 if the Secretary determines that, without ex-
2 planatory contributing factors (such as fur-
3 nishing emergent care services), a substantial
4 number of claims for such items under this sub-
5 section are for such items ordered by a physi-
6 cian or practitioner who has not previously
7 (during a period of not less than 24 months, as
8 established by the Secretary) furnished to the
9 individual involved any item or service for which
10 payment may be made under this title.

11 “(B) CLAIM REVIEW.—With respect to
12 items furnished on or after January 1, 2028,
13 that are included on the Master List pursuant
14 to subparagraph (A), if such an item is not sub-
15 ject to a determination of coverage in advance
16 pursuant to paragraph (15)(C), the Secretary
17 may conduct prepayment review of claims for
18 payment for such item.”.

19 (2) CONFORMING AMENDMENT FOR PROS-
20 THETIC DEVICES, ORTHOTICS, AND PROSTHETICS.—
21 Section 1834(h)(3) of the Social Security Act (42
22 U.S.C. 1395m(h)(3)) is amended by inserting “, and
23 paragraph (23) of subsection (a) shall apply to pros-
24 thetic devices, orthotics, and prosthetics in the same
25 manner as such provision applies to items for which

1 payment may be made under such subsection” be-
 2 fore the period at the end.

3 (b) REPORT ON IDENTIFYING CLINICAL DIAGNOSTIC
 4 LABORATORY TESTS AT HIGH RISK FOR FRAUD AND EF-
 5 FECTIVE MITIGATION MEASURES.—Not later than Janu-
 6 ary 1, 2026, the Inspector General of the Department of
 7 Health and Human Services shall submit to Congress a
 8 report assessing fraud risks relating to claims for clinical
 9 diagnostic laboratory tests for which payment may be
 10 made under section 1834A of the Social Security Act (42
 11 U.S.C. 1395m–1) and effective tools for reducing such
 12 fraudulent claims. The report may include information re-
 13 garding—

14 (1) which, if any, clinical diagnostic laboratory
 15 tests are identified as being at high risk of fraudu-
 16 lent claims, and an analysis of the factors that con-
 17 tribute to such risk;

18 (2) with respect to a clinical diagnostic labora-
 19 tory test identified under paragraph (1) as being at
 20 high risk of fraudulent claims—

21 (A) the amount payable under such section
 22 1834A with respect to such test;

23 (B) the number of such tests furnished to
 24 individuals enrolled under part B of title XVIII

1 of the Social Security Act (42 U.S.C. 1395j et
2 seq.);

3 (C) whether an order for such a test was
4 more likely to come from a provider with whom
5 the individual involved did not have a prior re-
6 lationship, as determined on the basis of prior
7 payment experience; and

8 (D) the frequency with which a claim for
9 payment under such section 1834A included the
10 payment modifier identified by code 59 or 91;
11 and

12 (3) suggested strategies for reducing the num-
13 ber of fraudulent claims made with respect to tests
14 so identified as being at high risk, including—

15 (A) an analysis of whether the Centers for
16 Medicare & Medicaid Services can detect aber-
17 rant billing patterns with respect to such tests
18 in a timely manner;

19 (B) any strategies for identifying and mon-
20 itoring the providers who are outliers with re-
21 spect to the number of such tests that such pro-
22 viders order; and

23 (C) targeted education efforts to mitigate
24 improper billing for such tests; and

1 (4) such other information as the Inspector
2 General determines appropriate.

3 **SEC. 213. GUIDANCE ON FURNISHING SERVICES VIA TELE-**
4 **HEALTH TO INDIVIDUALS WITH LIMITED**
5 **ENGLISH PROFICIENCY.**

6 (a) IN GENERAL.—Not later than 1 year after the
7 date of the enactment of this section, the Secretary of
8 Health and Human Services, in consultation with 1 or
9 more entities from each of the categories described in
10 paragraphs (1) through (7) of subsection (b), shall issue
11 and disseminate, or update and revise as applicable, guid-
12 ance for the entities described in such subsection on the
13 following:

14 (1) Best practices on facilitating and inte-
15 grating use of interpreters during a telemedicine ap-
16 pointment.

17 (2) Best practices on providing accessible in-
18 structions on how to access telecommunications sys-
19 tems (as such term is used for purposes of section
20 1834(m) of the Social Security Act (42 U.S.C.
21 1395m(m)) for individuals with limited English pro-
22 ficiency.

23 (3) Best practices on improving access to dig-
24 ital patient portals for individuals with limited
25 English proficiency.

1 (4) Best practices on integrating the use of
 2 video platforms that enable multi-person video calls
 3 furnished via a telecommunications system for pur-
 4 poses of providing interpretation during a telemedi-
 5 cine appointment for an individual with limited
 6 English proficiency.

7 (5) Best practices for providing patient mate-
 8 rials, communications, and instructions in multiple
 9 languages, including text message appointment re-
 10 minders and prescription information.

11 (b) ENTITIES DESCRIBED.—For purposes of sub-
 12 section (a), an entity described in this subsection is an
 13 entity in 1 or more of the following categories:

14 (1) Health information technology service pro-
 15 viders, including—

16 (A) electronic medical record companies;

17 (B) remote patient monitoring companies;

18 and

19 (C) telehealth or mobile health vendors and
 20 companies.

21 (2) Health care providers, including—

22 (A) physicians; and

23 (B) hospitals.

24 (3) Health insurers.

25 (4) Language service companies.

1 (5) Interpreter or translator professional asso-
2 ciations.

3 (6) Health and language services quality certifi-
4 cation organizations.

5 (7) Patient and consumer advocates, including
6 such advocates that work with individuals with lim-
7 ited English proficiency.

8 **SEC. 214. IN-HOME CARDIOPULMONARY REHABILITATION**
9 **FLEXIBILITIES.**

10 (a) IN GENERAL.—Section 1861(eee)(2) of the Social
11 Security Act (42 U.S.C. 1395x(eee)(2)) is amended—

12 (1) in subparagraph (A)(ii), by inserting “(in-
13 cluding, with respect to items and services furnished
14 through audio and video real-time communications
15 technology (excluding audio-only) on or after April
16 1, 2025, and before January 1, 2027, in the home
17 of an individual who is an outpatient of the hos-
18 pital)” after “outpatient basis”; and

19 (2) in subparagraph (B), by inserting “(includ-
20 ing, with respect to items and services furnished
21 through audio and video real-time communications
22 technology on or after April 1, 2025, and before
23 January 1, 2027, the virtual presence of such physi-
24 cian, physician assistant, nurse practitioner, or clin-
25 ical nurse specialist)” after “under the program”.

1 (b) PROGRAM INSTRUCTION AUTHORITY.—Notwith-
 2 standing any other provision of law, the Secretary of
 3 Health and Human Services may implement the amend-
 4 ments made by this section by program instruction or oth-
 5 erwise.

6 **SEC. 215. INCLUSION OF VIRTUAL DIABETES PREVENTION**
 7 **PROGRAM SUPPLIERS IN MDPP EXPANDED**
 8 **MODEL.**

9 (a) IN GENERAL.—Not later than January 1, 2026,
 10 the Secretary shall revise the regulations under parts 410
 11 and 424 of title 42, Code of Federal Regulations, to pro-
 12 vide that, for the period beginning January 1, 2026, and
 13 ending December 31, 2030—

14 (1) an entity may participate in the MDPP by
 15 offering only online MDPP services via synchronous
 16 or asynchronous technology or telecommunications if
 17 such entity meets the conditions for enrollment as
 18 an MDPP supplier (as specified in section
 19 424.205(b) of title 42, Code of Federal Regulations
 20 (or a successor regulation));

21 (2) if an entity participates in the MDPP in the
 22 manner described in paragraph (1)—

23 (A) the administrative location of such en-
 24 tity shall be the address of the entity on file

1 under the Diabetes Prevention Recognition Pro-
 2 gram; and

3 (B) in the case of online MDPP services
 4 furnished by such entity to an MDPP bene-
 5 ficiary who was not located in the same State
 6 as the entity at the time such services were fur-
 7 nished, the entity shall not be prohibited from
 8 submitting a claim for payment for such serv-
 9 ices solely by reason of the location of such ben-
 10 eficiary at such time; and

11 (3) no limit is applied on the number of times
 12 an individual may enroll in the MDPP.

13 (b) DEFINITIONS.—In this section:

14 (1) MDPP.—The term “MDPP” means the
 15 Medicare Diabetes Prevention Program conducted
 16 under section 1115A of the Social Security Act (42
 17 U.S.C. 1315a), as described in the final rule pub-
 18 lished in the Federal Register entitled “Medicare
 19 and Medicaid Programs; CY 2024 Payment Policies
 20 Under the Physician Fee Schedule and Other
 21 Changes to Part B Payment and Coverage Policies;
 22 Medicare Shared Savings Program Requirements;
 23 Medicare Advantage; Medicare and Medicaid Pro-
 24 vider and Supplier Enrollment Policies; and Basic

1 Health Program” (88 Fed. Reg. 78818 (November
2 16, 2023)) (or a successor regulation).

3 (2) REGULATORY TERMS.—The terms “Diabe-
4 tes Prevention Recognition Program”, “full CDC
5 DPRP recognition”, “MDPP beneficiary”, “MDPP
6 services”, and “MDPP supplier” have the meanings
7 given each such term in section 410.79(b) of title
8 42, Code of Federal Regulations.

9 (3) SECRETARY.—The term “Secretary” means
10 the Secretary of Health and Human Services.

11 **SEC. 216. MEDICATION-INDUCED MOVEMENT DISORDER**
12 **OUTREACH AND EDUCATION.**

13 Not later than January 1, 2026, the Secretary shall
14 use existing communications mechanisms to provide edu-
15 cation and outreach to physicians and appropriate non-
16 physician practitioners participating under the Medicare
17 program under title XVIII of the Social Security Act (42
18 U.S.C. 1395 et seq.) with respect to periodic screening for
19 medication-induced movement disorders that are associ-
20 ated with the treatment of mental health disorders in at-
21 risk patients, as well as resources related to clinical guide-
22 lines and best practices for furnishing such screening serv-
23 ices through telehealth. Such education and outreach shall
24 include information on how to account for such screening
25 services in evaluation and management code selection. The

1 Secretary shall, to the extent practicable, seek input from
2 relevant stakeholders to inform such education and out-
3 reach. Such education and outreach may also address
4 other relevant screening services furnished through tele-
5 health, as the Secretary determines appropriate.

6 **SEC. 217. REPORT ON WEARABLE MEDICAL DEVICES.**

7 Not later than 18 months after the date of the enact-
8 ment of this Act, the Comptroller General of the United
9 States shall conduct a technology assessment of, and sub-
10 mit to Congress a report on, the capabilities and limita-
11 tions of wearable medical devices used to support clinical
12 decision-making. Such report shall include a description
13 of—

14 (1) the potential for such devices to accurately
15 prescribe treatments;

16 (2) an examination of the benefits and chal-
17 lenges of artificial intelligence to augment such ca-
18 pabilities; and

19 (3) policy options to enhance the benefits and
20 mitigate potential challenges of developing or using
21 such devices.

1 **SEC. 218. EXTENSION OF TEMPORARY INCLUSION OF AU-**
 2 **THORIZED ORAL ANTIVIRAL DRUGS AS COV-**
 3 **ERED PART D DRUGS.**

4 Section 1860D–2(e)(1)(C) of the Social Security Act
 5 (42 U.S.C. 1395w–102(e)(1)(C)) is amended by striking
 6 “March 31, 2025” and inserting “December 31, 2025”.

7 **SEC. 219. EXTENSION OF ADJUSTMENT TO CALCULATION**
 8 **OF HOSPICE CAP AMOUNT.**

9 Section 1814(i)(2)(B) of the Social Security Act (42
 10 U.S.C. 1395f(i)(2)(B)) is amended—

11 (1) in clause (ii), by striking “2033” and in-
 12 serting “2034”; and

13 (2) in clause (iii), by striking “2033” and in-
 14 serting “2034”.

15 **SEC. 220. MULTIYEAR CONTRACTING AUTHORITY FOR**
 16 **MEDPAC AND MACPAC.**

17 Section 3904 of title 41, United States Code, is
 18 amended by adding at the end the following new sub-
 19 sections:

20 “(i) THE MEDICARE PAYMENT ADVISORY COMMIS-
 21 SION.—The Medicare Payment Advisory Commission may
 22 use available funds to enter into contracts for the procure-
 23 ment of severable services for a period that begins in one
 24 fiscal year and ends in the next fiscal year and may enter
 25 into multiyear contracts for the acquisition of property
 26 and services to the same extent as executive agencies

1 under the authority of sections 3902 and 3903 of this
2 title.

3 “(j) THE MEDICAID AND CHIP PAYMENT AND AC-
4 CESS COMMISSION.—The Medicaid and CHIP Payment
5 and Access Commission may use available funds to enter
6 into contracts for the procurement of severable services
7 for a period that begins in one fiscal year and ends in
8 the next fiscal year and may enter into multiyear contracts
9 for the acquisition of property and services to the same
10 extent as executive agencies under the authority of sec-
11 tions 3902 and 3903 of this title.”.

12 **SEC. 221. CONTRACTING PARITY FOR MEDPAC AND**
13 **MACPAC.**

14 In fiscal year 2025 and thereafter, for all contracts
15 for goods and services to which the Medicare and Payment
16 Advisory Commission or the Medicaid and CHIP Payment
17 and Access Commission is a party, the following Federal
18 Acquisition Regulation (FAR) clauses will apply: FAR
19 52.232–39 and FAR 52.233–4 (or a successor clause).

20 **SEC. 222. ADJUSTMENTS TO MEDICARE PART D COST-SHAR-**
21 **ING REDUCTIONS FOR LOW-INCOME INDIVID-**
22 **UALS.**

23 Section 1860D–14(a) of the Social Security Act (42
24 U.S.C. 1395w–114(a)) is amended—

(1) in paragraph (1)(D)(ii), by striking “that does not exceed \$1 for” and all that follows through the period at the end and inserting “that does not exceed—

“(I) for a plan year before 2027—

“(aa) for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)), \$1 or, if less, the copayment amount applicable to an individual under clause (iii); and

“(bb) for any other drug, \$3 or, if less, the copayment amount applicable to an individual under clause (iii); and

“(II) for plan year 2027 and each subsequent plan year—

“(aa) for a generic drug, \$0;

“(bb) for a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)), the dollar amount applied under this clause

1 for such a drug for the preceding
2 plan year, increased by the an-
3 nual percentage increase in the
4 consumer price index (all items;
5 U.S. city average) as of Sep-
6 tember of such preceding year,
7 or, if less, the copayment amount
8 applicable to an individual under
9 clause (iii); and

10 “(cc) for a drug not de-
11 scribed in either item (aa) or
12 (bb), the dollar amount applied
13 under this clause for such a drug
14 for the preceding plan year, in-
15 creased in the manner specified
16 in item (bb), or, if less, the co-
17 payment amount applicable to an
18 individual under clause (iii).

19 Any amount established under item (bb) or
20 (cc) of subclause (II), that is based on an
21 increase of \$1 or \$3, that is not a multiple
22 of 5 cents or 10 cents, respectively, shall
23 be rounded to the nearest multiple of 5
24 cents or 10 cents, respectively.”; and

1 (2) in paragraph (4)(A)(ii), by inserting “(be-
2 fore 2027)” after “a subsequent year”.

3 **SEC. 223. REQUIRING ENHANCED AND ACCURATE LISTS OF**
4 **(REAL) HEALTH PROVIDERS ACT.**

5 (a) IN GENERAL.—Section 1852(c) of the Social Se-
6 curity Act (42 U.S.C. 1395w–22(c)) is amended—

7 (1) in paragraph (1)(C)—

8 (A) by striking “plan, and any” and insert-
9 ing “plan, any”; and

10 (B) by inserting the following before the
11 period at the end: “, and, in the case of a speci-
12 fied MA plan (as defined in paragraph (3)(C)),
13 for plan year 2027 and subsequent plan years,
14 the information described in paragraph (3)(B)”;
15 and

16 (2) by adding at the end the following new
17 paragraph:

18 “(3) PROVIDER DIRECTORY ACCURACY.—

19 “(A) IN GENERAL.—For plan year 2027
20 and subsequent plan years, each MA organiza-
21 tion offering a specified MA plan (as defined in
22 subparagraph (C)) shall, for each such plan of-
23 fered by the organization—

24 “(i) maintain, on a publicly available
25 internet website, an accurate provider di-

1 rectory that includes the information de-
2 scribed in subparagraph (B);

3 “(ii) not less frequently than once
4 every 90 days (or, in the case of a hospital
5 or any other facility determined appro-
6 priate by the Secretary, at a lesser fre-
7 quency specified by the Secretary but in no
8 case less frequently than once every 12
9 months), verify the provider directory in-
10 formation of each provider listed in such
11 directory and, if applicable, update such
12 provider directory information;

13 “(iii) if the organization is unable to
14 verify such information with respect to a
15 provider, include in such directory an indi-
16 cation that the information of such pro-
17 vider may not be up-to-date; and

18 “(iv) remove a provider from such di-
19 rectory within 5 business days if the orga-
20 nization determines that the provider is no
21 longer a provider participating in the net-
22 work of such plan.

23 “(B) PROVIDER DIRECTORY INFORMA-
24 TION.—The information described in this sub-
25 paragraph is information enrollees may need to

1 access covered benefits from a provider with
 2 which such organization offering such plan has
 3 an agreement for furnishing items and services
 4 covered under such plan such as name, spe-
 5 cialty, contact information, primary office or fa-
 6 cility address, whether the provider is accepting
 7 new patients, accommodations for people with
 8 disabilities, cultural and linguistic capabilities,
 9 and telehealth capabilities.

10 “(C) SPECIFIED MA PLAN.—In this para-
 11 graph, the term ‘specified MA plan’ means—

12 “(i) a network-based plan (as defined
 13 in subsection (d)(5)(C)); or

14 “(ii) a Medicare Advantage private
 15 fee-for-service plan (as defined in section
 16 1859(b)(2)) that meets the access stand-
 17 ards under subsection (d)(4), in whole or
 18 in part, through entering into contracts or
 19 agreements as provided for under subpara-
 20 graph (B) of such subsection.”.

21 (b) ACCOUNTABILITY FOR PROVIDER DIRECTORY

22 ACCURACY.—

23 (1) COST SHARING FOR SERVICES FURNISHED
 24 BASED ON RELIANCE ON INCORRECT PROVIDER DI-
 25 RECTORY INFORMATION.—Section 1852(d) of the

1 Social Security Act (42 U.S.C. 1395w-22(d)) is
 2 amended—

3 (A) in paragraph (1)(C)—

4 (i) in clause (ii), by striking “or” at
 5 the end;

6 (ii) in clause (iii), by striking the
 7 semicolon at the end and inserting “, or”;
 8 and

9 (iii) by adding at the end the fol-
 10 lowing new clause:

11 “(iv) the services are furnished by a
 12 provider that is not participating in the
 13 network of a specified MA plan (as defined
 14 in subsection (c)(3)(C)) but is listed in the
 15 provider directory of such plan on the date
 16 on which the appointment is made, as de-
 17 scribed in paragraph (7)(A);” and

18 (B) by adding at the end the following new
 19 paragraph:

20 “(7) COST SHARING FOR SERVICES FURNISHED
 21 BASED ON RELIANCE ON INCORRECT PROVIDER DI-
 22 RECTORY INFORMATION.—

23 “(A) IN GENERAL.—For plan year 2027
 24 and subsequent plan years, if an enrollee is fur-
 25 nished an item or service by a provider that is

not participating in the network of a specified MA plan (as defined in subsection (c)(3)(C)) but is listed in the provider directory of such plan (as required to be provided to an enrollee pursuant to subsection (c)(1)(C)) on the date on which the appointment is made, and if such item or service would otherwise be covered under such plan if furnished by a provider that is participating in the network of such plan, the MA organization offering such plan shall ensure that the enrollee is only responsible for the lesser of—

“(i) the amount of cost sharing that would apply if such provider had been participating in the network of such plan; or

“(ii) the amount of cost sharing that would otherwise apply (without regard to this subparagraph).

“(B) NOTIFICATION REQUIREMENT.—For plan year 2027 and subsequent plan years, each MA organization that offers a specified MA plan shall—

“(i) notify enrollees of their cost-sharing protections under this paragraph and make such notifications, to the extent

practicable, by not later than the first day of an annual, coordinated election period under section 1851(e)(3) with respect to a year;

“(ii) include information regarding such cost-sharing protections in the provider directory of each specified MA plan offered by the MA organization.; and

“(iii) notify enrollees of their cost-sharing protections under this paragraph in an explanation of benefits.”.

(2) REQUIRED PROVIDER DIRECTORY ACCURACY ANALYSIS AND REPORTS.—

(A) IN GENERAL.—Section 1857(e) of the Social Security Act (42 U.S.C. 1395w–27(e)) is amended by adding at the end the following new paragraph:

“(6) PROVIDER DIRECTORY ACCURACY ANALYSIS AND REPORTS.—

“(A) IN GENERAL.—Beginning with plan years beginning on or after January 1, 2027, subject to subparagraph (C), a contract under this section with an MA organization shall require the organization, for each specified MA plan (as defined in section 1852(c)(3)(C)) of-

1 ferred by the organization to annually do the fol-
2 lowing:

3 “(i) Conduct an analysis estimating
4 the accuracy of the provider directory in-
5 formation of such plan using a random
6 sample of providers included in such pro-
7 vider directory as follows:

8 “(I) Such a random sample shall
9 include a random sample of each spe-
10 cialty of providers with a high inaccu-
11 racy rate of provider directory infor-
12 mation relative to other specialties of
13 providers, as determined by the Sec-
14 retary.

15 “(II) For purposes of subclause
16 (I), one type of specialty may be pro-
17 viders specializing in mental health or
18 substance use disorder treatment.

19 “(ii) Submit to the Secretary a report
20 containing the results of the analysis con-
21 ducted under clause (i), including an accu-
22 racy score for such provider directory in-
23 formation (as determined using a plan
24 verification method specified by the Sec-
25 retary under subparagraph (B)(i)).

1 “(B) DETERMINATION OF ACCURACY
2 SCORE.—

3 “(i) IN GENERAL.—The Secretary
4 shall specify plan verification methods,
5 such as using telephonic verification or
6 other approaches using data sources main-
7 tained by an MA organization or using
8 publicly available data sets, that MA orga-
9 nizations may use for estimating accuracy
10 scores of the provider directory information
11 of specified MA plans offered by such or-
12 ganizations.

13 “(ii) ACCURACY SCORE METHOD-
14 OLOGY.—With respect to each such meth-
15 od specified by the Secretary as described
16 in clause (i), the Secretary shall specify a
17 methodology for MA organizations to use
18 in estimating such accuracy scores. Each
19 such methodology shall take into account
20 the administrative burden on plans and
21 providers and the relative importance of
22 certain provider directory information on
23 enrollee ability to access care.

24 “(C) EXCEPTION.—The Secretary may
25 waive the requirements of this paragraph in the

1 case of a specified MA plan with low enrollment
2 (as defined by the Secretary).

3 “(D) TRANSPARENCY.—Beginning with
4 plan years beginning on or after January 1,
5 2028, the Secretary shall post accuracy scores
6 (as reported under subparagraph (A)(ii)), in a
7 machine readable file, on the internet website of
8 the Centers for Medicare & Medicaid Services.”.

9 (B) PROVISION OF INFORMATION TO
10 BENEFICIARIES.—Section 1851(d)(4) of the So-
11 cial Security Act (42 U.S.C. 1395w–21(d)(4))
12 is amended by adding at the end the following
13 new subparagraph:

14 “(F) PROVIDER DIRECTORY.—Beginning
15 with plan years beginning on or after January
16 1, 2028, the accuracy score of the plan’s pro-
17 vider directory (as reported under section
18 1857(e)(6)(A)(ii)) listed prominently on the
19 plan’s provider directory.”.

20 (C) FUNDING.—In addition to amounts
21 otherwise available, there is appropriated to the
22 Centers for Medicare & Medicaid Services Pro-
23 gram Management Account, out of any money
24 in the Treasury not otherwise appropriated,
25 \$4,000,000 for fiscal year 2025, to remain

1 available until expended, to carry out the
2 amendments made by this paragraph.

3 (3) GAO STUDY AND REPORT.—

4 (A) ANALYSIS.—The Comptroller General
5 of the United States (in this paragraph referred
6 to as the “Comptroller General”) shall conduct
7 a study of the implementation of the amend-
8 ments made by paragraphs (1) and (2). To the
9 extent data are available and reliable, such
10 study shall include an analysis of—

11 (i) the use of cost-sharing protections
12 required under section 1852(d)(7)(A) of
13 the Social Security Act, as added by para-
14 graph (1);

15 (ii) the trends in provider directory in-
16 formation accuracy scores under section
17 1857(e)(6)(A)(ii) of the Social Security
18 Act (as added by paragraph (2)(A)), both
19 overall and among providers specializing in
20 mental health or substance use disorder
21 treatment;

22 (iii) provider response rates by plan
23 verification methods;

1 (iv) administrative costs to providers
 2 and Medicare Advantage organizations;
 3 and

4 (v) other items determined appro-
 5 priate by the Comptroller General.

6 (B) REPORT.—Not later than January 15,
 7 2032, the Comptroller General shall submit to
 8 Congress a report containing the results of the
 9 study conducted under subparagraph (A), to-
 10 gether with recommendations for such legisla-
 11 tion and administrative action as the Comp-
 12 troller General determines appropriate.

13 (c) GUIDANCE ON MAINTAINING ACCURATE PRO-
 14 VIDER DIRECTORIES.—

15 (1) STAKEHOLDER MEETING.—

16 (A) IN GENERAL.—Not later than 3
 17 months after the date of enactment of this Act,
 18 the Secretary of Health and Human Services
 19 (referred to in this subsection as the “Sec-
 20 retary”) shall hold a public meeting to receive
 21 input on approaches for maintaining accurate
 22 provider directories for Medicare Advantage
 23 plans under part C of title XVIII of the Social
 24 Security Act (42 U.S.C. 1395w–21 et seq.), in-
 25 cluding input on approaches for reducing ad-

1 ministrative burden, such as data standardiza-
2 tion, and best practices to maintain accurate
3 provider directory information.

4 (B) PARTICIPANTS.—Participants of the
5 meeting under subparagraph (A) shall include
6 representatives from the Centers for Medicare &
7 Medicaid Services and the Assistant Secretary
8 for Technology Policy and Office of the Na-
9 tional Coordinator for Health Information
10 Technology. Such meeting shall be open to the
11 public. To the extent practicable, the Secretary
12 shall include health care providers, companies
13 that specialize in relevant technologies, health
14 insurers, and patient advocates.

15 (2) GUIDANCE TO MEDICARE ADVANTAGE OR-
16 GANIZATIONS.—Not later than 12 months after the
17 date of enactment of this Act, the Secretary shall
18 issue guidance to Medicare Advantage organizations
19 offering Medicare Advantage plans under part C of
20 title XVIII of the Social Security Act (42 U.S.C.
21 1395w–21 et seq.) on maintaining accurate provider
22 directories for such plans, taking into consideration
23 input received during the stakeholder meeting under
24 paragraph (1). Such guidance may include the fol-
25 lowing, as determined appropriate by the Secretary:

1 (A) Best practices for Medicare Advantage
2 organizations on how to work with providers to
3 maintain the accuracy of provider directories
4 and reduce provider and Medicare Advantage
5 organization burden with respect to maintaining
6 the accuracy of provider directories.

7 (B) Information on data sets and data
8 sources with information that could be used by
9 Medicare Advantage organizations to maintain
10 accurate provider directories.

11 (C) Approaches for utilizing data sources
12 maintained by Medicare Advantage organiza-
13 tions and publicly available data sets to main-
14 tain accurate provider directories.

15 (D) Information to be included in provider
16 directories that may be useful for Medicare
17 beneficiaries to assess plan networks when se-
18 lecting a plan and accessing providers partici-
19 pating in plan networks during the plan year.

20 (3) GUIDANCE TO PART B PROVIDERS.—Not
21 later than 12 months after the date of enactment of
22 this Act, the Secretary shall issue guidance to pro-
23 viders of services and suppliers who furnish items or
24 services for which benefits are available under part
25 B of title XVIII of the Social Security Act (42

1 U.S.C. 1395j et seq.) on when to update the Na-
 2 tional Plan and Provider Enumeration System for
 3 information changes.

4 **SEC. 224. MEDICARE COVERAGE OF MULTI-CANCER EARLY**
 5 **DETECTION SCREENING TESTS.**

6 (a) COVERAGE.—Section 1861 of the Social Security
 7 Act (42 U.S.C. 1395x) is amended—

8 (1) in subsection (s)(2)—

9 (A) by striking the semicolon at the end of
 10 subparagraph (JJ) and inserting “; and”; and

11 (B) by adding at the end the following new
 12 subparagraph:

13 “(KK) multi-cancer early detection screen-
 14 ing tests (as defined in subsection (nnn));”; and

15 (2) by adding at the end the following new sub-
 16 section:

17 “(nnn) MULTI-CANCER EARLY DETECTION SCREEN-
 18 ING TESTS.—

19 “(1) IN GENERAL.—The term ‘multi-cancer
 20 early detection screening test’ means a test fur-
 21 nished to an individual for the concurrent detection
 22 of multiple cancer types across multiple organ sites
 23 on or after January 1, 2029, that—

24 “(A) is cleared under section 510(k), clas-
 25 sified under section 513(f)(2), or approved

under section 515 of the Federal Food, Drug,
and Cosmetic Act;

“(B) is—

“(i) a genomic sequencing blood or
blood product test that includes the anal-
ysis of cell-free nucleic acids; or

“(ii) a test based on samples of bio-
logical material that provide results com-
parable to those obtained with a test de-
scribed in clause (i), as determined by the
Secretary; and

“(C) the Secretary determines is—

“(i) reasonable and necessary for the
prevention or early detection of an illness
or disability; and

“(ii) appropriate for individuals enti-
tled to benefits under part A or enrolled
under part B.

“(2) NCD PROCESS.—In making determina-
tions under paragraph (1)(C) regarding the coverage
of a new test, the Secretary shall use the process for
making national coverage determinations (as defined
in section 1869(f)(1)(B)) under this title.”.

(b) PAYMENT AND STANDARDS FOR MULTI-CANCER

EARLY DETECTION SCREENING TESTS.—

1 (1) IN GENERAL.—Section 1834 of the Social
 2 Security Act (42 U.S.C. 1395m) is amended by add-
 3 ing at the end the following new subsection:

4 “(aa) PAYMENT AND STANDARDS FOR MULTI-CAN-
 5 CER EARLY DETECTION SCREENING TESTS.—

6 “(1) PAYMENT AMOUNT.—The payment
 7 amount for a multi-cancer early detection screening
 8 test (as defined in section 1861(nnn)) is—

9 “(A) with respect to such a test furnished
 10 before January 1, 2031, equal to the payment
 11 amount in effect on the date of the enactment
 12 of this subsection for a multi-target stool
 13 screening DNA test covered pursuant to section
 14 1861(pp)(1)(D); and

15 “(B) with respect to such a test furnished
 16 on or after January 1, 2031, equal to the lesser
 17 of—

18 “(i) the amount described in subpara-
 19 graph (A); or

20 “(ii) the payment amount determined
 21 for such test under section 1834A.

22 “(2) LIMITATIONS.—

23 “(A) IN GENERAL.—No payment may be
 24 made under this part for a multi-cancer early

1 detection screening test furnished during a year
 2 to an individual if—

3 “(i) such individual—

4 “(I) is under 50 years of age; or

5 “(II) as of January 1 of such
 6 year, has attained the age specified in
 7 subparagraph (B) for such year; or

8 “(ii) such a test was furnished to the
 9 individual during the previous 11 months.

10 “(B) AGE SPECIFIED.—For purposes of
 11 subparagraph (A)(i)(II), the age specified in
 12 this subparagraph is—

13 “(i) for 2029, 65 years of age; and

14 “(ii) for a succeeding year, the age
 15 specified in this subparagraph for the pre-
 16 ceding year, increased by 1 year.

17 “(C) STANDARDS FOLLOWING USPSTF
 18 RATING OF A OR B.—In the case of a multi-can-
 19 cer early detection screening test that is rec-
 20 ommended with a grade of A or B by the
 21 United States Preventive Services Task Force,
 22 beginning on the date on which coverage for
 23 such test is provided pursuant to section
 24 1861(ddd)(1), the preceding provisions of this
 25 paragraph shall not apply.”.

1 (2) CONFORMING AMENDMENTS.—

2 (A) Section 1833 of the Social Security
3 Act (42 U.S.C. 1395l) is amended—

4 (i) in subsection (a)—

5 (I) in paragraph (1)(D)(i)(I), by
6 striking “section 1834(d)(1)” and in-
7 serting “subsection (d)(1) or (aa) of
8 section 1834”; and

9 (II) in paragraph (2)(D)(i)(I), by
10 striking “section 1834(d)(1)” and in-
11 serting “subsection (d)(1) or (aa) of
12 section 1834”; and

13 (ii) in subsection (h)(1)(A), by strik-
14 ing “section 1834(d)(1)” and inserting
15 “subsections (d)(1) and (aa) of section
16 1834”.

17 (B) Section 1862(a)(1)(A) of the Social
18 Security Act (42 U.S.C. 1395y(a)(1)(A)) is
19 amended—

20 (i) by striking “or additional preven-
21 tive services” and inserting “, additional
22 preventive services”; and

23 (ii) by inserting “, or multi-cancer
24 early detection screening tests (as defined

1 in section 1861(nnn))” after “(as de-
2 scribed in section 1861(ddd)(1))”.

3 (c) RULE OF CONSTRUCTION RELATING TO OTHER
4 CANCER SCREENING TESTS.—Nothing in this section, in-
5 cluding the amendments made by this section, shall be
6 construed—

7 (1) in the case of an individual who undergoes
8 a multi-cancer early detection screening test, to af-
9 fect coverage under part B of title XVIII of the So-
10 cial Security Act for other cancer screening tests
11 covered under such title, such as screening tests for
12 breast, cervical, colorectal, lung, or prostate cancer;
13 or

14 (2) in the case of an individual who undergoes
15 another cancer screening test, to affect coverage
16 under such part for a multi-cancer early detection
17 screening test or the use of such a test as a diag-
18 nostic or confirmatory test for a result of the other
19 cancer screening test.

20 **SEC. 225. MEDICARE COVERAGE OF EXTERNAL INFUSION**
21 **PUMPS AND NON-SELF-ADMINISTRABLE**
22 **HOME INFUSION DRUGS.**

23 (a) IN GENERAL.—Section 1861(n) of the Social Se-
24 curity Act (42 U.S.C. 1395x(n)) is amended by adding
25 at the end the following new sentence: “Beginning with

1 the first calendar quarter beginning on or after the date
2 that is 1 year after the date of the enactment of this sen-
3 tence, an external infusion pump and associated home in-
4 fusion drug (as defined in subsection (iii)(3)(C)) or other
5 associated supplies that do not meet the appropriate for
6 use in the home requirement applied to the definition of
7 durable medical equipment under section 414.202 of title
8 42, Code of Federal Regulations (or any successor to such
9 regulation) shall be treated as meeting such requirement
10 if each of the following criteria is satisfied:

11 “(1) The prescribing information approved by
12 the Food and Drug Administration for the home in-
13 fusion drug associated with the pump instructs that
14 the drug should be administered by or under the su-
15 pervision of a health care professional.

16 “(2) A qualified home infusion therapy supplier
17 (as defined in subsection (iii)(3)(D)) administers or
18 supervises the administration of the drug or biologi-
19 cal in a safe and effective manner in the patient’s
20 home (as defined in subsection (iii)(3)(B)).

21 “(3) The prescribing information described in
22 paragraph (1) instructs that the drug should be in-
23 fused at least 12 times per year—

24 “(A) intravenously or subcutaneously; or

1 “(B) at infusion rates that the Secretary
 2 determines would require the use of an external
 3 infusion pump.”.

4 (b) COST SHARING NOTIFICATION.—The Secretary
 5 of Health and Human Services shall ensure that patients
 6 are notified of the cost sharing for electing home infusion
 7 therapy compared to other applicable settings of care for
 8 the furnishing of infusion drugs under the Medicare pro-
 9 gram.

10 **SEC. 226. ASSURING PHARMACY ACCESS AND CHOICE FOR**
 11 **MEDICARE BENEFICIARIES.**

12 (a) IN GENERAL.—Section 1860D–4(b)(1) of the So-
 13 cial Security Act (42 U.S.C. 1395w–104(b)(1)) is amend-
 14 ed by striking subparagraph (A) and inserting the fol-
 15 lowing:

16 “(A) IN GENERAL.—

17 “(i) PARTICIPATION OF ANY WILLING
 18 PHARMACY.—A PDP sponsor offering a
 19 prescription drug plan shall permit any
 20 pharmacy that meets the standard contract
 21 terms and conditions under such plan to
 22 participate as a network pharmacy of such
 23 plan.

24 “(ii) CONTRACT TERMS AND CONDI-
 25 TIONS.—

1 “(I) IN GENERAL.—Notwith-
2 standing any other provision of law,
3 for plan years beginning on or after
4 January 1, 2028, in accordance with
5 clause (i), contract terms and condi-
6 tions offered by such PDP sponsor
7 shall be reasonable and relevant ac-
8 cording to standards established by
9 the Secretary under subclause (II).

10 “(II) STANDARDS.—Not later
11 than the first Monday in April of
12 2027, the Secretary shall establish
13 standards for reasonable and relevant
14 contract terms and conditions for pur-
15 poses of this clause.

16 “(III) REQUEST FOR INFORMA-
17 TION.—Not later than April 1, 2026,
18 for purposes of establishing the stand-
19 ards under subclause (II), the Sec-
20 retary shall issue a request for infor-
21 mation to seek input on trends in pre-
22 scription drug plan and network phar-
23 macy contract terms and conditions,
24 current prescription drug plan and
25 network pharmacy contracting prac-

1 tices, whether pharmacy reimburse-
2 ment and dispensing fees paid by
3 PDP sponsors to network pharmacies
4 sufficiently cover the ingredient and
5 operational costs of such pharmacies,
6 the use and application of pharmacy
7 quality measures by PDP sponsors for
8 network pharmacies, PDP sponsor re-
9 strictions or limitations on the dis-
10 pensing of covered part D drugs by
11 network pharmacies (or any subsets of
12 such pharmacies), PDP sponsor au-
13 diting practices for network phar-
14 macies, areas in current regulations or
15 program guidance related to con-
16 tracting between prescription drug
17 plans and network pharmacies requir-
18 ing clarification or additional speci-
19 ficity, factors for consideration in de-
20 termining the reasonableness and rel-
21 evance of contract terms and condi-
22 tions between prescription drug plans
23 and network pharmacies, and other
24 issues as determined appropriate by
25 the Secretary.”.

1 (b) ESSENTIAL RETAIL PHARMACIES.—Section
2 1860D–42 of the Social Security Act (42 U.S.C. 1395w–
3 152) is amended by adding at the end the following new
4 subsection:

5 “(e) ESSENTIAL RETAIL PHARMACIES.—

6 “(1) IN GENERAL.—With respect to plan years
7 beginning on or after January 1, 2028, the Sec-
8 retary shall publish reports, at least once every 2
9 years until 2034, and periodically thereafter, that
10 provide information, to the extent feasible, on—

11 “(A) trends in ingredient cost reimburse-
12 ment, dispensing fees, incentive payments and
13 other fees paid by PDP sponsors offering pre-
14 scription drug plans and MA organizations of-
15 fering MA–PD plans under this part to essen-
16 tial retail pharmacies (as defined in paragraph
17 (2)) with respect to the dispensing of covered
18 part D drugs, including a comparison of such
19 trends between essential retail pharmacies and
20 pharmacies that are not essential retail phar-
21 macies;

22 “(B) trends in amounts paid to PDP spon-
23 sors offering prescription drug plans and MA
24 organizations offering MA–PD plans under this
25 part by essential retail pharmacies with respect

1 to the dispensing of covered part D drugs, in-
2 cluding a comparison of such trends between
3 essential retail pharmacies and pharmacies that
4 are not essential retail pharmacies;

5 “(C) trends in essential retail pharmacy
6 participation in pharmacy networks and pre-
7 ferred pharmacy networks for prescription drug
8 plans offered by PDP sponsors and MA–PD
9 plans offered by MA organizations under this
10 part, including a comparison of such trends be-
11 tween essential retail pharmacies and phar-
12 macies that are not essential retail pharmacies;

13 “(D) trends in the number of essential re-
14 tail pharmacies, including variation in such
15 trends by geographic region or other factors;

16 “(E) a comparison of cost-sharing for cov-
17 ered part D drugs dispensed by essential retail
18 pharmacies that are network pharmacies for
19 prescription drug plans offered by PDP spon-
20 sors and MA–PD plans offered by MA organi-
21 zations under this part and cost-sharing for
22 covered part D drugs dispensed by other net-
23 work pharmacies for such plans located in simi-
24 lar geographic areas that are not essential retail
25 pharmacies;

“(F) a comparison of the volume of covered part D drugs dispensed by essential retail pharmacies that are network pharmacies for prescription drug plans offered by PDP sponsors and MA–PD plans offered by MA organizations under this part and such volume of dispensing by network pharmacies for such plans located in similar geographic areas that are not essential retail pharmacies, including information on any patterns or trends in such comparison specific to certain types of covered part D drugs, such as generic drugs or drugs specified as specialty drugs by a PDP sponsor under a prescription drug plan or an MA organization under an MA–PD plan; and

“(G) a comparison of the information described in subparagraphs (A) through (F) between essential retail pharmacies that are network pharmacies for prescription drug plans offered by PDP sponsors under this part and essential retail pharmacies that are network pharmacies for MA–PD plans offered by MA organizations under this part.

“(2) DEFINITION OF ESSENTIAL RETAIL PHARMACY.—In this subsection, the term ‘essential retail

pharmacy’ means, with respect to a plan year, a retail pharmacy that—

“(A) is not a pharmacy that is an affiliate as defined in paragraph (4); and

“(B) is located in—

“(i) a medically underserved area (as designated pursuant to section 330(b)(3)(A) of the Public Health Service Act);

“(ii) a rural area in which there is no other retail pharmacy within 10 miles, as determined by the Secretary;

“(iii) a suburban area in which there is no other retail pharmacy within 2 miles, as determined by the Secretary; or

“(iv) an urban area in which there is no other retail pharmacy within 1 mile, as determined by the Secretary.

“(3) LIST OF ESSENTIAL RETAIL PHARMACIES.—

“(A) PUBLICATION OF LIST OF ESSENTIAL RETAIL PHARMACIES.—For each plan year (beginning with plan year 2028), the Secretary shall publish, on a publicly available internet website of the Centers for Medicare & Medicaid

1 Services, a list of pharmacies that meet the cri-
2 teria described in subparagraphs (A) and (B) of
3 paragraph (2) to be considered an essential re-
4 tail pharmacy.

5 “(B) REQUIRED SUBMISSIONS FROM PDP
6 SPONSORS.—For each plan year (beginning
7 with plan year 2028), each PDP sponsor offer-
8 ing a prescription drug plan and each MA orga-
9 nization offering an MA–PD plan shall submit
10 to the Secretary, for the purposes of deter-
11 mining retail pharmacies that meet the criterion
12 specified in subparagraph (A) of paragraph (2),
13 a list of retail pharmacies that are affiliates of
14 such sponsor or organization, or are affiliates of
15 a pharmacy benefit manager acting on behalf of
16 such sponsor or organization, at a time, and in
17 a form and manner, specified by the Secretary.

18 “(C) REPORTING BY PDP SPONSORS AND
19 MA ORGANIZATIONS.—For each plan year be-
20 ginning with plan year 2027, each PDP sponsor
21 offering a prescription drug plan and each MA
22 organization offering an MA–PD plan under
23 this part shall submit to the Secretary informa-
24 tion on incentive payments and other fees paid
25 by such sponsor or organization to pharmacies,

1 insofar as any such payments or fees are not
 2 otherwise reported, at a time, and in a form
 3 and manner, specified by the Secretary.

4 “(D) IMPLEMENTATION.—Notwithstanding
 5 any other provision of law, the Secretary may
 6 implement this paragraph by program instruc-
 7 tion or otherwise.

8 “(E) NONAPPLICATION OF PAPERWORK
 9 REDUCTION ACT.—Chapter 35 of title 44,
 10 United States Code, shall not apply to the im-
 11 plementation of this paragraph.

12 “(4) DEFINITION OF AFFILIATE; PHARMACY
 13 BENEFIT MANAGER.—In this subsection, the terms
 14 ‘affiliate’ and ‘pharmacy benefit manager’ have the
 15 meaning given those terms in section 1860D–
 16 12(h)(7).”.

17 (c) ENFORCEMENT.—

18 (1) IN GENERAL.—Section 1860D–4(b)(1) of
 19 the Social Security Act (42 U.S.C. 1395w–
 20 104(b)(1)) is amended by adding at the end the fol-
 21 lowing new subparagraph:

22 “(F) ENFORCEMENT OF STANDARDS FOR
 23 REASONABLE AND RELEVANT CONTRACT TERMS
 24 AND CONDITIONS.—

1 “(i) ALLEGATION SUBMISSION PROC-
2 ESS.—

3 “(I) IN GENERAL.—Not later
4 than January 1, 2028, the Secretary
5 shall establish a process through
6 which a pharmacy may submit to the
7 Secretary an allegation of a violation
8 by a PDP sponsor offering a prescrip-
9 tion drug plan of the standards for
10 reasonable and relevant contract
11 terms and conditions under subpara-
12 graph (A)(ii), or of subclause (VIII)
13 of this clause.

14 “(II) FREQUENCY OF SUBMIS-
15 SION.—

16 “(aa) IN GENERAL.—Except
17 as provided in item (bb), the alle-
18 gation submission process under
19 this clause shall allow pharmacies
20 to submit any allegations of vio-
21 lations described in subclause (I)
22 not more frequently than once
23 per plan year per contract be-
24 tween a pharmacy and a PDP
25 sponsor.

1 “(bb) ALLEGATIONS RELAT-
2 ING TO CONTRACT MODIFICA-
3 TIONS.—In the case where a con-
4 tract between a pharmacy and a
5 PDP sponsor is modified fol-
6 lowing the submission of allega-
7 tions by a pharmacy with respect
8 to such contract and plan year,
9 the allegation submission process
10 under this clause shall allow such
11 pharmacy to submit an additional
12 allegation related to those modi-
13 fications with respect to such
14 contract and plan year.

15 “(III) ACCESS TO RELEVANT
16 DOCUMENTS AND MATERIALS.—A
17 PDP sponsor subject to an allegation
18 under this clause—

19 “(aa) shall provide docu-
20 ments or materials, as specified
21 by the Secretary, including con-
22 tract offers made by such spon-
23 sor to such pharmacy or cor-
24 respondence related to such of-
25 fers, to the Secretary at a time,

1 and in a form and manner, speci-
2 fied by the Secretary; and

3 “(bb) shall not prohibit or
4 otherwise limit the ability of a
5 pharmacy to submit such docu-
6 ments or materials to the Sec-
7 retary for the purpose of submit-
8 ting an allegation or providing
9 evidence for such an allegation
10 under this clause.

11 “(IV) STANDARDIZED TEM-
12 PLATE.—The Secretary shall establish
13 a standardized template for phar-
14 macies to use for the submission of al-
15 legations described in subclause (I).
16 Such template shall require that the
17 submission include a certification by
18 the pharmacy that the information in-
19 cluded is accurate, complete, and true
20 to the best of the knowledge, informa-
21 tion, and belief of such pharmacy.

22 “(V) PREVENTING FRIVOLOUS
23 ALLEGATIONS.—In the case where the
24 Secretary determines that a pharmacy
25 has submitted frivolous allegations

1 under this clause on a routine basis,
2 the Secretary may temporarily pro-
3 hibit such pharmacy from using the
4 allegation submission process under
5 this clause, as determined appropriate
6 by the Secretary.

7 “(VI) EXEMPTION FROM FREE-
8 DOM OF INFORMATION ACT.—Allega-
9 tions submitted under this clause shall
10 be exempt from disclosure under sec-
11 tion 552 of title 5, United States
12 Code.

13 “(VII) RULE OF CONSTRUC-
14 TION.—Nothing in this clause shall be
15 construed as limiting the ability of a
16 pharmacy to pursue other legal ac-
17 tions or remedies, consistent with ap-
18 plicable Federal or State law, with re-
19 spect to a potential violation of a re-
20 quirement described in this subpara-
21 graph.

22 “(VIII) ANTI-RETALIATION AND
23 ANTI-COERCION.—Consistent with ap-
24 plicable Federal or State law, a PDP
25 sponsor shall not—

1 “(aa) retaliate against a
2 pharmacy for submitting any al-
3 legations under this clause; or

4 “(bb) coerce, intimidate,
5 threaten, or interfere with the
6 ability of a pharmacy to submit
7 any such allegations.

8 “(ii) INVESTIGATION.—The Secretary
9 shall investigate, as determined appro-
10 priate by the Secretary, allegations sub-
11 mitted pursuant to clause (i).

12 “(iii) ENFORCEMENT.—

13 “(I) IN GENERAL.—In the case
14 where the Secretary determines that a
15 PDP sponsor offering a prescription
16 drug plan has violated the standards
17 for reasonable and relevant contract
18 terms and conditions under subpara-
19 graph (A)(ii), the Secretary may use
20 authorities under sections 1857(g)
21 and 1860D–12(b)(3)(E) to impose
22 civil monetary penalties or other inter-
23 mediate sanctions.

24 “(II) APPLICATION OF CIVIL
25 MONETARY PENALTIES.—The provi-

1 sions of section 1128A (other than
 2 subsections (a) and (b)) shall apply to
 3 a civil monetary penalty under this
 4 clause in the same manner as such
 5 provisions apply to a penalty or pro-
 6 ceeding under section 1128A(a).”.

7 (2) CONFORMING AMENDMENT.—Section
 8 1857(g)(1) of the Social Security Act (42 U.S.C.
 9 1395w–27(g)(1)) is amended—

10 (A) in subparagraph (J), by striking “or”
 11 after the semicolon;

12 (B) by redesignating subparagraph (K) as
 13 subparagraph (L);

14 (C) by inserting after subparagraph (J),
 15 the following new subparagraph:

16 “(K) fails to comply with the standards for
 17 reasonable and relevant contract terms and con-
 18 ditions under subparagraph (A)(ii) of section
 19 1860D–4(b)(1); or”;

20 (D) in subparagraph (L), as redesignated
 21 by subparagraph (B), by striking “through (J)”
 22 and inserting “through (K)”; and

23 (E) in the flush matter following subpara-
 24 graph (L), as so redesignated, by striking “sub-

1 paragraphs (A) through (K)” and inserting
 2 “subparagraphs (A) through (L)”.

3 (d) ACCOUNTABILITY OF PHARMACY BENEFIT MAN-
 4 AGERS FOR VIOLATIONS OF REASONABLE AND RELEVANT
 5 CONTRACT TERMS AND CONDITIONS.—

6 (1) IN GENERAL.—Section 1860D–12(b) of the
 7 Social Security Act (42 U.S.C. 1395w–112) is
 8 amended by adding at the end the following new
 9 paragraph:

10 “(9) ACCOUNTABILITY OF PHARMACY BENEFIT
 11 MANAGERS FOR VIOLATIONS OF REASONABLE AND
 12 RELEVANT CONTRACT TERMS AND CONDITIONS.—
 13 For plan years beginning on or after January 1,
 14 2028, each contract entered into with a PDP spon-
 15 sor under this part with respect to a prescription
 16 drug plan offered by such sponsor shall provide that
 17 any pharmacy benefit manager acting on behalf of
 18 such sponsor has a written agreement with the PDP
 19 sponsor under which the pharmacy benefit manager
 20 agrees to reimburse the PDP sponsor for any
 21 amounts paid by such sponsor under section 1860D–
 22 4(b)(1)(F)(iii)(I) to the Secretary as a result of a
 23 violation described in such section if such violation
 24 is related to a responsibility delegated to the phar-
 25 macy benefit manager by such PDP sponsor.”.

1 (2) MA–PD PLANS.—Section 1857(f)(3) of the
 2 Social Security Act (42 U.S.C. 1395w–27(f)(3)) is
 3 amended by adding at the end the following new
 4 subparagraph:

5 “(F) ACCOUNTABILITY OF PHARMACY
 6 BENEFIT MANAGERS FOR VIOLATIONS OF REA-
 7 SONABLE AND RELEVANT CONTRACT TERMS.—
 8 For plan years beginning on or after January
 9 1, 2028, section 1860D–12(b)(9).”.

10 (e) BIENNIAL REPORT ON ENFORCEMENT AND
 11 OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—
 12 Section 1860D–42 of the Social Security Act (42 U.S.C.
 13 1395w–152), as amended by subsection (b), is amended
 14 by adding at the end the following new subsection:

15 “(f) BIENNIAL REPORT ON ENFORCEMENT AND
 16 OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—

17 “(1) IN GENERAL.—Not later than 2 years
 18 after the date of enactment of this subsection, and
 19 at least once every 2 years thereafter, the Secretary
 20 shall publish a report on enforcement and oversight
 21 actions and activities undertaken by the Secretary
 22 with respect to the requirements under section
 23 1860D–4(b)(1).

24 “(2) LIMITATION.—A report under paragraph
 25 (1) shall not disclose—

1 “(A) identifiable information about individ-
 2 uals or entities unless such information is oth-
 3 erwise publicly available; or

4 “(B) trade secrets with respect to any enti-
 5 ties.”.

6 (f) FUNDING.—In addition to amounts otherwise
 7 available, there is appropriated to the Centers for Medi-
 8 care & Medicaid Services Program Management Account,
 9 out of any money in the Treasury not otherwise appro-
 10 priated, \$188,000,000 for fiscal year 2025, to remain
 11 available until expended, to carry out this section.

12 **SEC. 227. MODERNIZING AND ENSURING PBM ACCOUNT-**
 13 **ABILITY.**

14 (a) IN GENERAL.—

15 (1) PRESCRIPTION DRUG PLANS.—Section
 16 1860D–12 of the Social Security Act (42 U.S.C.
 17 1395w–112) is amended by adding at the end the
 18 following new subsection:

19 “(h) REQUIREMENTS RELATING TO PHARMACY BEN-
 20 EFIT MANAGERS.—For plan years beginning on or after
 21 January 1, 2028:

22 “(1) AGREEMENTS WITH PHARMACY BENEFIT
 23 MANAGERS.—Each contract entered into with a
 24 PDP sponsor under this part with respect to a pre-
 25 scription drug plan offered by such sponsor shall

1 provide that any pharmacy benefit manager acting
2 on behalf of such sponsor has a written agreement
3 with the PDP sponsor under which the pharmacy
4 benefit manager, and any affiliates of such phar-
5 macy benefit manager, as applicable, agree to meet
6 the following requirements:

7 “(A) NO INCOME OTHER THAN BONA FIDE
8 SERVICE FEES.—

9 “(i) IN GENERAL.—The pharmacy
10 benefit manager and any affiliate of such
11 pharmacy benefit manager shall not derive
12 any remuneration with respect to any serv-
13 ices provided on behalf of any entity or in-
14 dividual, in connection with the utilization
15 of covered part D drugs, from any such en-
16 tity or individual other than bona fide serv-
17 ice fees, subject to clauses (ii) and (iii).

18 “(ii) INCENTIVE PAYMENTS.—For the
19 purposes of this subsection, an incentive
20 payment (as determined by the Secretary)
21 paid by a PDP sponsor to a pharmacy
22 benefit manager that is performing serv-
23 ices on behalf of such sponsor shall be
24 deemed a ‘bona fide service fee’ (even if
25 such payment does not otherwise meet the

1 definition of such term under paragraph
2 (7)(B)) if such payment is a flat dollar
3 amount, is consistent with fair market
4 value (as specified by the Secretary), is re-
5 lated to services actually performed by the
6 pharmacy benefit manager or affiliate of
7 such pharmacy benefit manager, on behalf
8 of the PDP sponsor making such payment,
9 in connection with the utilization of cov-
10 ered part D drugs, and meets additional
11 requirements, if any, as determined appro-
12 priate by the Secretary.

13 “(iii) CLARIFICATION ON REBATES
14 AND DISCOUNTS USED TO LOWER COSTS
15 FOR COVERED PART D DRUGS.—Rebates,
16 discounts, and other price concessions re-
17 ceived by a pharmacy benefit manager or
18 an affiliate of a pharmacy benefit manager
19 from manufacturers, even if such price
20 concessions are calculated as a percentage
21 of a drug’s price, shall not be considered a
22 violation of the requirements of clause (i)
23 if they are fully passed through to a PDP
24 sponsor and are compliant with all regu-
25 latory and subregulatory requirements re-

1 lated to direct and indirect remuneration
2 for manufacturer rebates under this part,
3 including in cases where a PDP sponsor is
4 acting as a pharmacy benefit manager on
5 behalf of a prescription drug plan offered
6 by such PDP sponsor.

7 “(iv) EVALUATION OF REMUNERATION
8 ARRANGEMENTS.—Components of subsets
9 of remuneration arrangements (such as
10 fees or other forms of compensation paid
11 to or retained by the pharmacy benefit
12 manager or affiliate of such pharmacy ben-
13 efit manager), as determined appropriate
14 by the Secretary, between pharmacy ben-
15 efit managers or affiliates of such phar-
16 macy benefit managers, as applicable, and
17 other entities involved in the dispensing or
18 utilization of covered part D drugs (includ-
19 ing PDP sponsors, manufacturers, phar-
20 macies, and other entities as determined
21 appropriate by the Secretary) shall be sub-
22 ject to review by the Secretary, in con-
23 sultation with the Office of the Inspector
24 General of the Department of Health and
25 Human Services, as determined appro-

1 appropriate by the Secretary. The Secretary, in
 2 consultation with the Office of the Inspec-
 3 tor General, shall review whether remu-
 4 neration under such arrangements is con-
 5 sistent with fair market value (as specified
 6 by the Secretary) through reviews and as-
 7 sessments of such remuneration, as deter-
 8 mined appropriate.

9 “(v) DISGORGEMENT.—The pharmacy
 10 benefit manager shall disgorge any remu-
 11 nation paid to such pharmacy benefit
 12 manager or an affiliate of such pharmacy
 13 benefit manager in violation of this sub-
 14 paragraph to the PDP sponsor.

15 “(vi) ADDITIONAL REQUIREMENTS.—
 16 The pharmacy benefit manager shall—

17 “(I) enter into a written agree-
 18 ment with any affiliate of such phar-
 19 macy benefit manager, under which
 20 the affiliate shall identify and disgorge
 21 any remuneration described in clause
 22 (v) to the pharmacy benefit manager;
 23 and

24 “(II) attest, subject to any re-
 25 quirements determined appropriate by

1 the Secretary, that the pharmacy ben-
 2 efit manager has entered into a writ-
 3 ten agreement described in subclause
 4 (I) with any relevant affiliate of the
 5 pharmacy benefit manager.

6 “(B) TRANSPARENCY REGARDING GUARAN-
 7 TEES AND COST PERFORMANCE EVALUA-
 8 TIONS.—The pharmacy benefit manager shall—

9 “(i) define, interpret, and apply, in a
 10 fully transparent and consistent manner
 11 for purposes of calculating or otherwise
 12 evaluating pharmacy benefit manager per-
 13 formance against pricing guarantees or
 14 similar cost performance measurements re-
 15 lated to rebates, discounts, price conces-
 16 sions, or net costs, terms such as—

17 “(I) ‘generic drug’, in a manner
 18 consistent with the definition of the
 19 term under section 423.4 of title 42,
 20 Code of Federal Regulations, or a suc-
 21 cessor regulation;

22 “(II) ‘brand name drug’, in a
 23 manner consistent with the definition
 24 of the term under section 423.4 of

1 title 42, Code of Federal Regulations,
2 or a successor regulation;

3 “(III) ‘specialty drug’;

4 “(IV) ‘rebate’; and

5 “(V) ‘discount’;

6 “(ii) identify any drugs, claims, or
7 price concessions excluded from any pric-
8 ing guarantee or other cost performance
9 measure in a clear and consistent manner;
10 and

11 “(iii) where a pricing guarantee or
12 other cost performance measure is based
13 on a pricing benchmark other than the
14 wholesale acquisition cost (as defined in
15 section 1847A(c)(6)(B)) of a drug, cal-
16 culate and provide a wholesale acquisition
17 cost-based equivalent to the pricing guar-
18 antee or other cost performance measure.

19 “(C) PROVISION OF INFORMATION.—

20 “(i) IN GENERAL.—Not later than
21 July 1 of each year, beginning in 2028, the
22 pharmacy benefit manager shall submit to
23 the PDP sponsor, and to the Secretary, a
24 report, in accordance with this subpara-
25 graph, and shall make such report avail-

1 able to such sponsor at no cost to such
2 sponsor in a format specified by the Sec-
3 retary under paragraph (5). Each such re-
4 port shall include, with respect to such
5 PDP sponsor and each plan offered by
6 such sponsor, the following information
7 with respect to the previous plan year:

8 “(I) A list of all drugs covered by
9 the plan that were dispensed includ-
10 ing, with respect to each such drug—

11 “(aa) the brand name, ge-
12 neric or non-proprietary name,
13 and National Drug Code;

14 “(bb) the number of plan
15 enrollees for whom the drug was
16 dispensed, the total number of
17 prescription claims for the drug
18 (including original prescriptions
19 and refills, counted as separate
20 claims), and the total number of
21 dosage units of the drug dis-
22 pensed;

23 “(cc) the number of pre-
24 scription claims described in item
25 (bb) by each type of dispensing

1 channel through which the drug
2 was dispensed, including retail,
3 mail order, specialty pharmacy,
4 long term care pharmacy, home
5 infusion pharmacy, or other types
6 of pharmacies or providers;

7 “(dd) the average wholesale
8 acquisition cost, listed as cost per
9 day’s supply, cost per dosage
10 unit, and cost per typical course
11 of treatment (as applicable);

12 “(ee) the average wholesale
13 price for the drug, listed as price
14 per day’s supply, price per dos-
15 age unit, and price per typical
16 course of treatment (as applica-
17 ble);

18 “(ff) the total out-of-pocket
19 spending by plan enrollees on
20 such drug after application of
21 any benefits under the plan, in-
22 cluding plan enrollee spending
23 through copayments, coinsurance,
24 and deductibles;

1 “(gg) total rebates paid by
2 the manufacturer on the drug as
3 reported under the Detailed DIR
4 Report (or any successor report)
5 submitted by such sponsor to the
6 Centers for Medicare & Medicaid
7 Services;

8 “(hh) all other direct or in-
9 direct remuneration on the drug
10 as reported under the Detailed
11 DIR Report (or any successor re-
12 port) submitted by such sponsor
13 to the Centers for Medicare &
14 Medicaid Services;

15 “(ii) the average pharmacy
16 reimbursement amount paid by
17 the plan for the drug in the ag-
18 gregate and disaggregated by dis-
19 pensing channel identified in item
20 (cc);

21 “(jj) the average National
22 Average Drug Acquisition Cost
23 (NADAC); and

24 “(kk) total manufacturer-de-
25 rived revenue, inclusive of bona

1 fide service fees, attributable to
2 the drug and retained by the
3 pharmacy benefit manager and
4 any affiliate of such pharmacy
5 benefit manager.

6 “(II) In the case of a pharmacy
7 benefit manager that has an affiliate
8 that is a retail, mail order, or spe-
9 cialty pharmacy, with respect to drugs
10 covered by such plan that were dis-
11 pensed, the following information:

12 “(aa) The percentage of
13 total prescriptions that were dis-
14 pensed by pharmacies that are an
15 affiliate of the pharmacy benefit
16 manager for each drug.

17 “(bb) The interquartile
18 range of the total combined costs
19 paid by the plan and plan enroll-
20 ees, per dosage unit, per course
21 of treatment, per 30-day supply,
22 and per 90-day supply for each
23 drug dispensed by pharmacies
24 that are not an affiliate of the
25 pharmacy benefit manager and

1 that are included in the phar-
2 macy network of such plan.

3 “(cc) The interquartile
4 range of the total combined costs
5 paid by the plan and plan enroll-
6 ees, per dosage unit, per course
7 of treatment, per 30-day supply,
8 and per 90-day supply for each
9 drug dispensed by pharmacies
10 that are an affiliate of the phar-
11 macy benefit manager and that
12 are included in the pharmacy
13 network of such plan.

14 “(dd) The lowest total com-
15 bined cost paid by the plan and
16 plan enrollees, per dosage unit,
17 per course of treatment, per 30-
18 day supply, and per 90-day sup-
19 ply, for each drug that is avail-
20 able from any pharmacy included
21 in the pharmacy network of such
22 plan.

23 “(ee) The difference between
24 the average acquisition cost of
25 the affiliate, such as a pharmacy

1 or other entity that acquires pre-
2 scription drugs, that initially ac-
3 quires the drug and the amount
4 reported under subclause (I)(jj)
5 for each drug.

6 “(ff) A list inclusive of the
7 brand name, generic or non-pro-
8 prietary name, and National
9 Drug Code of covered part D
10 drugs subject to an agreement
11 with a covered entity under sec-
12 tion 340B of the Public Health
13 Service Act for which the phar-
14 macy benefit manager or an affil-
15 iate of the pharmacy benefit
16 manager had a contract or other
17 arrangement with such a covered
18 entity in the service area of such
19 plan.

20 “(III) Where a drug approved
21 under section 505(c) of the Federal
22 Food, Drug, and Cosmetic Act (re-
23 ferred to in this subclause as the ‘list-
24 ed drug’) is covered by the plan, the
25 following information:

1 “(aa) A list of currently
2 marketed generic drugs approved
3 under section 505(j) of the Fed-
4 eral Food, Drug, and Cosmetic
5 Act pursuant to an application
6 that references such listed drug
7 that are not covered by the plan,
8 are covered on the same for-
9 mulary tier or a formulary tier
10 typically associated with higher
11 cost-sharing than the listed drug,
12 or are subject to utilization man-
13 agement that the listed drug is
14 not subject to.

15 “(bb) The estimated average
16 beneficiary cost-sharing under
17 the plan for a 30-day supply of
18 the listed drug.

19 “(cc) Where a generic drug
20 listed under item (aa) is on a for-
21 mulary tier typically associated
22 with higher cost-sharing than the
23 listed drug, the estimated aver-
24 age cost-sharing that a bene-
25 ficiary would have paid for a 30-

1 day supply of each of the generic
2 drugs described in item (aa), had
3 the plan provided coverage for
4 such drugs on the same for-
5 mulary tier as the listed drug.

6 “(dd) A written justification
7 for providing more favorable cov-
8 erage of the listed drug than the
9 generic drugs described in item
10 (aa).

11 “(ee) The number of cur-
12 rently marketed generic drugs
13 approved under section 505(j) of
14 the Federal Food, Drug, and
15 Cosmetic Act pursuant to an ap-
16 plication that references such
17 listed drug.

18 “(IV) Where a reference product
19 (as defined in section 351(i) of the
20 Public Health Service Act) is covered
21 by the plan, the following information:

22 “(aa) A list of currently
23 marketed biosimilar biological
24 products licensed under section
25 351(k) of the Public Health

1 Service Act pursuant to an appli-
2 cation that refers to such ref-
3 erence product that are not cov-
4 ered by the plan, are covered on
5 the same formulary tier or a for-
6 mulary tier typically associated
7 with higher cost-sharing than the
8 reference product, or are subject
9 to utilization management that
10 the reference product is not sub-
11 ject to.

12 “(bb) The estimated average
13 beneficiary cost-sharing under
14 the plan for a 30-day supply of
15 the reference product.

16 “(cc) Where a biosimilar bi-
17 ological product listed under item
18 (aa) is on a formulary tier typi-
19 cally associated with higher cost-
20 sharing than the reference prod-
21 uct, the estimated average cost-
22 sharing that a beneficiary would
23 have paid for a 30-day supply of
24 each of the biosimilar biological
25 products described in item (aa),

1 had the plan provided coverage
2 for such products on the same
3 formulary tier as the reference
4 product.

5 “(dd) A written justification
6 for providing more favorable cov-
7 erage of the reference product
8 than the biosimilar biological
9 product described in item (aa).

10 “(ee) The number of cur-
11 rently marketed biosimilar bio-
12 logical products licensed under
13 section 351(k) of the Public
14 Health Service Act, pursuant to
15 an application that refers to such
16 reference product.

17 “(V) Total gross spending on
18 covered part D drugs by the plan, not
19 net of rebates, fees, discounts, or
20 other direct or indirect remuneration.

21 “(VI) The total amount retained
22 by the pharmacy benefit manager or
23 an affiliate of such pharmacy benefit
24 manager in revenue related to utiliza-
25 tion of covered part D drugs under

1 that plan, inclusive of bona fide serv-
2 ice fees.

3 “(VII) The total spending on cov-
4 ered part D drugs net of rebates, fees,
5 discounts, or other direct and indirect
6 remuneration by the plan.

7 “(VIII) An explanation of any
8 benefit design parameters under such
9 plan that encourage plan enrollees to
10 fill prescriptions at pharmacies that
11 are an affiliate of such pharmacy ben-
12 efit manager, such as mail and spe-
13 cialty home delivery programs, and re-
14 tail and mail auto-refill programs.

15 “(IX) The following information:

16 “(aa) A list of all brokers,
17 consultants, advisors, and audi-
18 tors that receive compensation
19 from the pharmacy benefit man-
20 ager or an affiliate of such phar-
21 macy benefit manager for refer-
22 rals, consulting, auditing, or
23 other services offered to PDP
24 sponsors related to pharmacy
25 benefit management services.

1 “(bb) The amount of com-
 2 pensation provided by such phar-
 3 macy benefit manager or affiliate
 4 to each such broker, consultant,
 5 advisor, and auditor.

6 “(cc) The methodology for
 7 calculating the amount of com-
 8 pensation provided by such phar-
 9 macy benefit manager or affil-
 10 iate, for each such broker, con-
 11 sultant, advisor, and auditor.

12 “(X) A list of all affiliates of the
 13 pharmacy benefit manager.

14 “(XI) A summary document sub-
 15 mitted in a standardized template de-
 16 veloped by the Secretary that includes
 17 such information described in sub-
 18 clauses (I) through (X).

19 “(ii) WRITTEN EXPLANATION OF CON-
 20 TRACTS OR AGREEMENTS WITH DRUG
 21 MANUFACTURERS.—

22 “(I) IN GENERAL.—The phar-
 23 macy benefit manager shall, not later
 24 than 30 days after the finalization of
 25 any contract or agreement between

1 such pharmacy benefit manager or an
2 affiliate of such pharmacy benefit
3 manager and a drug manufacturer (or
4 subsidiary, agent, or entity affiliated
5 with such drug manufacturer) that
6 makes rebates, discounts, payments,
7 or other financial incentives related to
8 one or more covered part D drugs or
9 other prescription drugs, as applica-
10 ble, of the manufacturer directly or
11 indirectly contingent upon coverage,
12 formulary placement, or utilization
13 management conditions on any other
14 covered part D drugs or other pre-
15 scription drugs, as applicable, submit
16 to the PDP sponsor a written expla-
17 nation of such contract or agreement.

18 “(II) REQUIREMENTS.—A writ-
19 ten explanation under subclause (I)
20 shall—

21 “(aa) include the manufac-
22 turer subject to the contract or
23 agreement, all covered part D
24 drugs and other prescription
25 drugs, as applicable, subject to

1 the contract or agreement and
2 the manufacturers of such drugs,
3 and a high-level description of
4 the terms of such contract or
5 agreement and how such terms
6 apply to such drugs; and

7 “(bb) be certified by the
8 Chief Executive Officer, Chief Fi-
9 nancial Officer, or General Coun-
10 sel of such pharmacy benefit
11 manager, or affiliate of such
12 pharmacy benefit manager, as
13 applicable, or an individual dele-
14 gated with the authority to sign
15 on behalf of one of these officers,
16 who reports directly to the offi-
17 cer.

18 “(III) DEFINITION OF OTHER
19 PRESCRIPTION DRUGS.—For purposes
20 of this clause, the term ‘other pre-
21 scription drugs’ means prescription
22 drugs covered as supplemental bene-
23 fits under this part or prescription
24 drugs paid outside of this part.

25 “(D) AUDIT RIGHTS.—

1 “(i) IN GENERAL.—Not less than once
2 a year, at the request of the PDP sponsor,
3 the pharmacy benefit manager shall allow
4 for an audit of the pharmacy benefit man-
5 ager to ensure compliance with all terms
6 and conditions under the written agree-
7 ment described in this paragraph and the
8 accuracy of information reported under
9 subparagraph (C).

10 “(ii) AUDITOR.—The PDP sponsor
11 shall have the right to select an auditor.
12 The pharmacy benefit manager shall not
13 impose any limitations on the selection of
14 such auditor.

15 “(iii) PROVISION OF INFORMATION.—
16 The pharmacy benefit manager shall make
17 available to such auditor all records, data,
18 contracts, and other information necessary
19 to confirm the accuracy of information
20 provided under subparagraph (C), subject
21 to reasonable restrictions on how such in-
22 formation must be reported to prevent re-
23 disclosure of such information.

24 “(iv) TIMING.—The pharmacy benefit
25 manager must provide information under

1 clause (iii) and other information, data,
 2 and records relevant to the audit to such
 3 auditor within 6 months of the initiation of
 4 the audit and respond to requests for addi-
 5 tional information from such auditor with-
 6 in 30 days after the request for additional
 7 information.

8 “(v) INFORMATION FROM AFFILI-
 9 ATES.—The pharmacy benefit manager
 10 shall be responsible for providing to such
 11 auditor information required to be reported
 12 under subparagraph (C) or under clause
 13 (iii) of this subparagraph that is owned or
 14 held by an affiliate of such pharmacy ben-
 15 efit manager.

16 “(2) ENFORCEMENT.—

17 “(A) IN GENERAL.—Each PDP sponsor
 18 shall—

19 “(i) disgorge to the Secretary any
 20 amounts disgorged to the PDP sponsor by
 21 a pharmacy benefit manager under para-
 22 graph (1)(A)(v);

23 “(ii) require, in a written agreement
 24 with any pharmacy benefit manager acting
 25 on behalf of such sponsor or affiliate of

1 such pharmacy benefit manager, that such
2 pharmacy benefit manager or affiliate re-
3 imburse the PDP sponsor for any civil
4 money penalty imposed on the PDP spon-
5 sor as a result of the failure of the phar-
6 macy benefit manager or affiliate to meet
7 the requirements of paragraph (1) that are
8 applicable to the pharmacy benefit man-
9 ager or affiliate under the agreement; and

10 “(iii) require, in a written agreement
11 with any such pharmacy benefit manager
12 acting on behalf of such sponsor or affil-
13 iate of such pharmacy benefit manager,
14 that such pharmacy benefit manager or af-
15 filiate be subject to punitive remedies for
16 breach of contract for failure to comply
17 with the requirements applicable under
18 paragraph (1).

19 “(B) REPORTING OF ALLEGED VIOLA-
20 TIONS.—The Secretary shall make available and
21 maintain a mechanism for manufacturers, PDP
22 sponsors, pharmacies, and other entities that
23 have contractual relationships with pharmacy
24 benefit managers or affiliates of such pharmacy
25 benefit managers to report, on a confidential

1 basis, alleged violations of paragraph (1)(A) or
2 subparagraph (C).

3 “(C) ANTI-RETALIATION AND ANTI-COER-
4 CION.—Consistent with applicable Federal or
5 State law, a PDP sponsor shall not—

6 “(i) retaliate against an individual or
7 entity for reporting an alleged violation
8 under subparagraph (B); or

9 “(ii) coerce, intimidate, threaten, or
10 interfere with the ability of an individual
11 or entity to report any such alleged viola-
12 tions.

13 “(3) CERTIFICATION OF COMPLIANCE.—

14 “(A) IN GENERAL.—Each PDP sponsor
15 shall furnish to the Secretary (at a time and in
16 a manner specified by the Secretary) an annual
17 certification of compliance with this subsection,
18 as well as such information as the Secretary de-
19 termines necessary to carry out this subsection.

20 “(B) IMPLEMENTATION.—Notwithstanding
21 any other provision of law, the Secretary may
22 implement this paragraph by program instruc-
23 tion or otherwise.

24 “(4) RULE OF CONSTRUCTION.—Nothing in
25 this subsection shall be construed as—

“(A) prohibiting flat dispensing fees or reimbursement or payment for ingredient costs (including customary, industry-standard discounts directly related to drug acquisition that are retained by pharmacies or wholesalers) to entities that acquire or dispense prescription drugs; or

“(B) modifying regulatory requirements or sub-regulatory program instruction or guidance related to pharmacy payment, reimbursement, or dispensing fees.

“(5) STANDARD FORMATS.—

“(A) IN GENERAL.—Not later than June 1, 2027, the Secretary shall specify standard, machine-readable formats for pharmacy benefit managers to submit annual reports required under paragraph (1)(C)(i).

“(B) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

“(6) CONFIDENTIALITY.—

“(A) IN GENERAL.—Information disclosed by a pharmacy benefit manager, an affiliate of a pharmacy benefit manager, a PDP sponsor,

1 or a pharmacy under this subsection that is not
2 otherwise publicly available or available for pur-
3 chase shall not be disclosed by the Secretary or
4 a PDP sponsor receiving the information, ex-
5 cept that the Secretary may disclose the infor-
6 mation for the following purposes:

7 “(i) As the Secretary determines nec-
8 essary to carry out this part.

9 “(ii) To permit the Comptroller Gen-
10 eral to review the information provided.

11 “(iii) To permit the Director of the
12 Congressional Budget Office to review the
13 information provided.

14 “(iv) To permit the Executive Direc-
15 tor of the Medicare Payment Advisory
16 Commission to review the information pro-
17 vided.

18 “(v) To the Attorney General for the
19 purposes of conducting oversight and en-
20 forcement under this title.

21 “(vi) To the Inspector General of the
22 Department of Health and Human Serv-
23 ices in accordance with its authorities
24 under the Inspector General Act of 1978

1 (section 406 of title 5, United States
2 Code), and other applicable statutes.

3 “(B) RESTRICTION ON USE OF INFORMA-
4 TION.—The Secretary, the Comptroller General,
5 the Director of the Congressional Budget Of-
6 fice, and the Executive Director of the Medicare
7 Payment Advisory Commission shall not report
8 on or disclose information disclosed pursuant to
9 subparagraph (A) to the public in a manner
10 that would identify—

11 “(i) a specific pharmacy benefit man-
12 ager, affiliate, pharmacy, manufacturer,
13 wholesaler, PDP sponsor, or plan; or

14 “(ii) contract prices, rebates, dis-
15 counts, or other remuneration for specific
16 drugs in a manner that may allow the
17 identification of specific contracting parties
18 or of such specific drugs.

19 “(7) DEFINITIONS.—For purposes of this sub-
20 section:

21 “(A) AFFILIATE.—The term ‘affiliate’
22 means, with respect to any pharmacy benefit
23 manager or PDP sponsor, any entity that, di-
24 rectly or indirectly—

1 “(i) owns or is owned by, controls or
2 is controlled by, or is otherwise related in
3 any ownership structure to such pharmacy
4 benefit manager or PDP sponsor; or

5 “(ii) acts as a contractor, principal, or
6 agent to such pharmacy benefit manager
7 or PDP sponsor, insofar as such con-
8 tractor, principal, or agent performs any of
9 the functions described under subpara-
10 graph (C).

11 “(B) BONA FIDE SERVICE FEE.—The term
12 ‘bona fide service fee’ means a fee that is reflec-
13 tive of the fair market value (as specified by the
14 Secretary, through notice and comment rule-
15 making) for a bona fide, itemized service actu-
16 ally performed on behalf of an entity, that the
17 entity would otherwise perform (or contract for)
18 in the absence of the service arrangement and
19 that is not passed on in whole or in part to a
20 client or customer, whether or not the entity
21 takes title to the drug. Such fee must be a flat
22 dollar amount and shall not be directly or indi-
23 rectly based on, or contingent upon—

1 “(i) drug price, such as wholesale ac-
 2 quisition cost or drug benchmark price
 3 (such as average wholesale price);

4 “(ii) the amount of discounts, rebates,
 5 fees, or other direct or indirect remunera-
 6 tion with respect to covered part D drugs
 7 dispensed to enrollees in a prescription
 8 drug plan, except as permitted pursuant to
 9 paragraph (1)(A)(ii);

10 “(iii) coverage or formulary placement
 11 decisions or the volume or value of any re-
 12 ferrals or business generated between the
 13 parties to the arrangement; or

14 “(iv) any other amounts or meth-
 15 odologies prohibited by the Secretary.

16 “(C) PHARMACY BENEFIT MANAGER.—The
 17 term ‘pharmacy benefit manager’ means any
 18 person or entity that, either directly or through
 19 an intermediary, acts as a price negotiator or
 20 group purchaser on behalf of a PDP sponsor or
 21 prescription drug plan, or manages the pre-
 22 scription drug benefits provided by such spon-
 23 sor or plan, including the processing and pay-
 24 ment of claims for prescription drugs, the per-
 25 formance of drug utilization review, the proc-

1 essing of drug prior authorization requests, the
 2 adjudication of appeals or grievances related to
 3 the prescription drug benefit, contracting with
 4 network pharmacies, controlling the cost of cov-
 5 ered part D drugs, or the provision of related
 6 services. Such term includes any person or enti-
 7 ty that carries out one or more of the activities
 8 described in the preceding sentence, irrespective
 9 of whether such person or entity calls itself a
 10 ‘pharmacy benefit manager’.”.

11 (2) MA–PD PLANS.—Section 1857(f)(3) of the
 12 Social Security Act (42 U.S.C. 1395w–27(f)(3)), as
 13 amended by section 226(d)(2), is amended by adding
 14 at the end the following new subparagraph:

15 “(G) REQUIREMENTS RELATING TO PHAR-
 16 MACY BENEFIT MANAGERS.—For plan years be-
 17 ginning on or after January 1, 2028, section
 18 1860D–12(h).”.

19 (3) NONAPPLICATION OF PAPERWORK REDUC-
 20 TION ACT.—Chapter 35 of title 44, United States
 21 Code, shall not apply to the implementation of this
 22 subsection.

23 (4) FUNDING.—

24 (A) SECRETARY.—In addition to amounts
 25 otherwise available, there is appropriated to the

Centers for Medicare & Medicaid Services Program Management Account, out of any money in the Treasury not otherwise appropriated, \$113,000,000 for fiscal year 2025, to remain available until expended, to carry out this subsection.

(B) OIG.—In addition to amounts otherwise available, there is appropriated to the Inspector General of the Department of Health and Human Services, out of any money in the Treasury not otherwise appropriated, \$20,000,000 for fiscal year 2025, to remain available until expended, to carry out this subsection.

(b) GAO STUDY AND REPORT ON PRICE-RELATED COMPENSATION ACROSS THE SUPPLY CHAIN.—

(1) STUDY.—The Comptroller General of the United States (in this subsection referred to as the “Comptroller General”) shall conduct a study describing the use of compensation and payment structures related to a prescription drug’s price within the retail prescription drug supply chain in part D of title XVIII of the Social Security Act (42 U.S.C. 1395w–101 et seq.). Such study shall summarize information from Federal agencies and industry ex-

perts, to the extent available, with respect to the following:

(A) The type, magnitude, other features (such as the pricing benchmarks used), and prevalence of compensation and payment structures related to a prescription drug's price, such as calculating fee amounts as a percentage of a prescription drug's price, between intermediaries in the prescription drug supply chain, including—

- (i) pharmacy benefit managers;
- (ii) PDP sponsors offering prescription drug plans and Medicare Advantage organizations offering MA–PD plans;
- (iii) drug wholesalers;
- (iv) pharmacies;
- (v) manufacturers;
- (vi) pharmacy services administrative organizations;
- (vii) brokers, auditors, consultants, and other entities that—

(I) advise PDP sponsors offering prescription drug plans and Medicare Advantage organizations offering MA–

1 PD plans regarding pharmacy bene-
2 fits; or

3 (II) review PDP sponsor and
4 Medicare Advantage organization con-
5 tracts with pharmacy benefit man-
6 agers; and

7 (viii) other service providers that con-
8 tract with any of the entities described in
9 clauses (i) through (vii) that may use
10 price-related compensation and payment
11 structures, such as rebate aggregators (or
12 other entities that negotiate or process
13 price concessions on behalf of pharmacy
14 benefit managers, plan sponsors, or phar-
15 macies).

16 (B) The primary business models and com-
17 pensation structures for each category of inter-
18 mediary described in subparagraph (A).

19 (C) Variation in price-related compensation
20 structures between affiliated entities (such as
21 entities with common ownership, either full or
22 partial, and subsidiary relationships) and unaf-
23 filiated entities.

24 (D) Potential conflicts of interest among
25 contracting entities related to the use of pre-

1 scription drug price-related compensation struc-
2 tures, such as the potential for fees or other
3 payments set as a percentage of a prescription
4 drug's price to advantage formulary selection,
5 distribution, or purchasing of prescription drugs
6 with higher prices.

7 (E) Notable differences, if any, in the use
8 and level of price-based compensation struc-
9 tures over time and between different market
10 segments, such as under part D of title XVIII
11 of the Social Security Act (42 U.S.C. 1395w-
12 101 et seq.) and the Medicaid program under
13 title XIX of such Act (42 U.S.C. 1396 et seq.).

14 (F) The effects of drug price-related com-
15 pensation structures and alternative compensa-
16 tion structures on Federal health care programs
17 and program beneficiaries, including with re-
18 spect to cost-sharing, premiums, Federal out-
19 lays, biosimilar and generic drug adoption and
20 utilization, drug shortage risks, and the poten-
21 tial for fees set as a percentage of a drug's
22 price to advantage the formulary selection, dis-
23 tribution, or purchasing of drugs with higher
24 prices.

1 (G) Other issues determined to be relevant
2 and appropriate by the Comptroller General.

3 (2) REPORT.—Not later than 2 years after the
4 date of enactment of this section, the Comptroller
5 General shall submit to Congress a report containing
6 the results of the study conducted under paragraph
7 (1), together with recommendations for such legisla-
8 tion and administrative action as the Comptroller
9 General determines appropriate.

10 (c) MEDPAC REPORTS ON AGREEMENTS WITH
11 PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRE-
12 SCRIPTIION DRUG PLANS AND MA–PD PLANS.—

13 (1) IN GENERAL.—The Medicare Payment Ad-
14 visory Commission shall submit to Congress the fol-
15 lowing reports:

16 (A) INITIAL REPORT.—Not later than the
17 first March 15 occurring after the date that is
18 2 years after the date on which the Secretary
19 makes the data available to the Commission, a
20 report regarding agreements with pharmacy
21 benefit managers with respect to prescription
22 drug plans and MA–PD plans. Such report
23 shall include, to the extent practicable—

24 (i) a description of trends and pat-
25 terns, including relevant averages, totals,

1 and other figures for the types of informa-
2 tion submitted;

3 (ii) an analysis of any differences in
4 agreements and their effects on plan en-
5 rollee out-of-pocket spending and average
6 pharmacy reimbursement, and other im-
7 pacts; and

8 (iii) any recommendations the Com-
9 mission determines appropriate.

10 (B) FINAL REPORT.—Not later than 2
11 years after the date on which the Commission
12 submits the initial report under subparagraph
13 (A), a report describing any changes with re-
14 spect to the information described in subpara-
15 graph (A) over time, together with any rec-
16 ommendations the Commission determines ap-
17 propriate.

18 (2) FUNDING.—In addition to amounts other-
19 wise available, there is appropriated to the Medicare
20 Payment Advisory Commission, out of any money in
21 the Treasury not otherwise appropriated,
22 \$1,000,000 for fiscal year 2025, to remain available
23 until expended, to carry out this subsection.

1 **SEC. 228. REQUIRING A SEPARATE IDENTIFICATION NUM-**
2 **BER AND AN ATTESTATION FOR EACH OFF-**
3 **CAMPUS OUTPATIENT DEPARTMENT OF A**
4 **PROVIDER.**

5 (a) IN GENERAL.—Section 1833(t) of the Social Se-
6 curity Act (42 U.S.C. 1395l(t)) is amended by adding at
7 the end the following new paragraph:

8 “(23) USE OF UNIQUE HEALTH IDENTIFIERS;
9 ATTESTATION.—

10 “(A) IN GENERAL.—No payment may be
11 made under this subsection (or under an appli-
12 cable payment system pursuant to paragraph
13 (21)) for items and services furnished on or
14 after January 1, 2026, by an off-campus out-
15 patient department of a provider (as defined in
16 subparagraph (C)) unless—

17 “(i) such department has obtained,
18 and such items and services are billed
19 under, a standard unique health identifier
20 for health care providers (as described in
21 section 1173(b)) that is separate from
22 such identifier for such provider;

23 “(ii) such provider has submitted to
24 the Secretary, during the 2-year period
25 ending on the date such items and services
26 are so furnished, an initial provider-based

1 status attestation that such department is
2 compliant with the requirements described
3 in section 413.65 of title 42, Code of Fed-
4 eral Regulations (or a successor regula-
5 tion); and

6 “(iii) after such provider has sub-
7 mitted an attestation under clause (ii),
8 such provider has submitted a subsequent
9 attestation within the timeframe specified
10 by the Secretary.

11 “(B) PROCESS FOR SUBMISSION AND RE-
12 VIEW.—Not later than 1 year after the date of
13 enactment of this paragraph, the Secretary
14 shall, through notice and comment rulemaking,
15 establish a process for each provider with an
16 off-campus outpatient department of a provider
17 to submit an initial and subsequent attestation
18 pursuant to clauses (ii) and (iii), respectively, of
19 subparagraph (A), and for the Secretary to re-
20 view each such attestation and determine,
21 through site visits, remote audits, or other
22 means (as determined appropriate by the Sec-
23 retary), whether such department is compliant
24 with the requirements described in such sub-
25 paragraph.

“(C) OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER DEFINED.—For purposes of this paragraph, the term ‘off-campus outpatient department of a provider’ means a department of a provider (as defined in section 413.65 of title 42, Code of Federal Regulations, or any successor regulation) that is not located—

“(i) on the campus (as defined in such section) of such provider; or

“(ii) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section).”.

(b) HHS OIG ANALYSIS.—Not later than January 1, 2030, the Inspector General of the Department of Health and Human Services shall submit to Congress—

(1) an analysis of the process established by the Secretary of Health and Human Services to conduct the reviews and determinations described in section 1833(t)(23)(B) of the Social Security Act, as added by subsection (a) of this section; and

(2) recommendations based on such analysis, as the Inspector General determines appropriate.

1 **SEC. 229. MEDICARE SEQUESTRATION.**

2 Section 251A(6) of the Balanced Budget and Emer-
3 gency Deficit Control Act of 1985 (2 U.S.C. 901a(6)) is
4 amended—

5 (1) in subparagraph (D), by striking “such
6 that,” and all that follows and inserting “such that
7 the payment reduction shall be 2.0 percent.”; and

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

9 “(F) On the date on which the President sub-
10 mits the budget under section 1105 of title 31,
11 United States Code, for fiscal year 2033, the Presi-
12 dent shall order a sequestration of payments for the
13 Medicare programs specified in section 256(d), effec-
14 tive upon issuance, such that, notwithstanding the 2
15 percent limit specified in subparagraph (A) for such
16 payments—

17 “(i) with respect to the first 2 months in
18 which such order is effective for such fiscal
19 year, the payment reduction shall be 2.0 per-
20 cent; and

21 “(ii) with respect to the last 10 months in
22 which such order is effective for such fiscal
23 year, the payment reduction shall be 0 per-
24 cent.”.

1 **SEC. 230. MEDICARE IMPROVEMENT FUND.**

2 Section 1898(b)(1) of the Social Security Act (42
3 U.S.C. 1395iii(b)(1)) is amended by striking
4 “\$1,251,000,000” and inserting “\$1,938,000,000”.

5 **TITLE III—HUMAN SERVICES**

6 **SEC. 301. SEXUAL RISK AVOIDANCE EDUCATION EXTEN-**
7 **SION.**

8 Section 510 of the Social Security Act (42 U.S.C.
9 710) is amended—

10 (1) in subsection (a)—

11 (A) in paragraph (1)—

12 (i) by striking “and for the period”
13 and inserting “for the period”;

14 (ii) by inserting “for the period begin-
15 ning on April 1, 2025, and ending on Sep-
16 tember 30, 2025, and for the period begin-
17 ning on October 1, 2025, and ending on
18 December 31, 2025,” before “allot to each
19 State”; and

20 (iii) by striking “for fiscal year 2024
21 or 2025” and inserting “for fiscal year
22 2024, 2025, or 2026”; and

23 (B) in paragraph (2), by striking “or
24 2025” each place it appears and inserting “,
25 2025, or 2026”; and

1 (2) in subsection (f)(1), by striking “and for
 2 the period beginning on October 1, 2024, and ending
 3 on March 31, 2025, an amount equal to the pro rata
 4 portion of the amount appropriated for the cor-
 5 responding period for fiscal year 2024” and insert-
 6 ing “for the period beginning on October 1, 2024,
 7 and ending on March 31, 2025, and for the period
 8 beginning on April 1, 2025, and ending on Sep-
 9 tember 30, 2025, an amount equal to the pro rata
 10 portion of the amount appropriated for the cor-
 11 responding period for fiscal year 2024, and for the
 12 period beginning on October 1, 2025, and ending on
 13 December 31, 2025, an amount equal to the pro
 14 rata portion of the amount appropriated for the cor-
 15 responding period for fiscal year 2025”

16 **SEC. 302. PERSONAL RESPONSIBILITY EDUCATION EXTEN-**
 17 **SION.**

18 Section 513 of the Social Security Act (42 U.S.C.
 19 713) is amended—

20 (1) in subsection (a)(1)—

21 (A) in subparagraph (A), in the matter
 22 preceding clause (i)—

23 (i) by striking “and for the period”
 24 and inserting “for the period”; and

1 (ii) by inserting “for the period begin-
 2 ning on April 1, 2025, and ending on Sep-
 3 tember 30, 2025, and for the period begin-
 4 ning on October 1, 2025, and ending on
 5 December 31, 2025,” before “the Sec-
 6 retary shall allot”; and

7 (B) in subparagraph (B)(i)—

8 (i) by striking “and for the period”
 9 and inserting “for the period”; and

10 (ii) by inserting “, for the period be-
 11 ginning on April 1, 2025, and ending on
 12 September 30, 2025, and for the period
 13 beginning on October 1, 2025, and ending
 14 on December 31, 2025” before the period;

15 (2) in subsection (c)(3), by striking “fiscal year
 16 2024 or 2025” and inserting “fiscal year 2024,
 17 2025, or 2026”; and

18 (3) in subsection (f), by striking “and for the
 19 period beginning on October 1, 2024, and ending on
 20 March 31, 2025, an amount equal to the pro rata
 21 portion of the amount appropriated for the cor-
 22 responding period for fiscal year 2024” and insert-
 23 ing “for the period beginning on October 1, 2024,
 24 and ending on March 31, 2025, and for the period
 25 beginning on April 1, 2025, and ending on Sep-

1 tember 30, 2025, an amount equal to the pro rata
2 portion of the amount appropriated for the cor-
3 responding period for fiscal year 2024, and for the
4 period beginning on October 1, 2025, and ending on
5 December 31, 2025, an amount equal to the pro
6 rata portion of the amount appropriated for the cor-
7 responding period for fiscal year 2025”.

8 **SEC. 303. EXTENSION OF FUNDING FOR FAMILY-TO-FAMILY**
9 **HEALTH INFORMATION CENTERS.**

10 Section 501(c)(1)(A)(viii) of the Social Security Act
11 (42 U.S.C. 701(c)(1)(A)(viii)) is amended—

12 (1) by striking “\$3,000,000” and inserting
13 “\$7,500,000”; and

14 (2) by striking “for the portion of fiscal year
15 2025 before April 1, 2025” and inserting “for the
16 period beginning on October 1, 2024, and ending on
17 December 31, 2025”.

TITLE IV—PUBLIC HEALTH EXTENDERS

Subtitle A—Extensions

SEC. 401. EXTENSION FOR COMMUNITY HEALTH CENTERS, NATIONAL HEALTH SERVICE CORPS, AND TEACHING HEALTH CENTERS THAT OPERATE GME PROGRAMS.

(a) EXTENSION FOR COMMUNITY HEALTH CENTERS.—Section 10503(b)(1) of the Patient Protection and Affordable Care Act (42 U.S.C. 254b–2(b)(1)) is amended—

(1) in subparagraph (H), by striking “and” at the end;

(2) in subparagraph (I), by striking the period and inserting “, and \$2,315,342,466 for the period beginning on April 1, 2025, and ending on September 30, 2025; and”;

(3) by adding at the end the following:

“(J) \$4,600,000,000 for fiscal year 2026; and”.

(b) EXTENSION FOR THE NATIONAL HEALTH SERVICE CORPS.—Section 10503(b)(2) of the Patient Protection and Affordable Care Act (42 U.S.C. 254b–2(b)(2)) is amended—

1 (1) in subparagraph (I), by striking “and” at
2 the end;

3 (2) in subparagraph (J), by striking the period
4 and inserting “, and \$176,712,329 for the period be-
5 ginning on April 1, 2025, and ending on September
6 30, 2025; and”;

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

8 “(J) \$350,000,000 for fiscal year 2026.”.

9 (c) TEACHING HEALTH CENTERS THAT OPERATE
10 GRADUATE MEDICAL EDUCATION PROGRAMS.—Section
11 340H(g)(1) of the Public Health Service Act (42 U.S.C.
12 256h(g)(1)) is amended—

13 (1) in subparagraph (D), by striking “; and”
14 and inserting a semicolon;

15 (2) in subparagraph (E), by striking the period
16 and inserting a semicolon; and

17 (3) by adding at the end the following: “

18 “(F) \$112,849,315 for the period begin-
19 ning on January 1, 2025, and ending on Sep-
20 tember 30, 2025;

21 “(G) \$225,000,000 for fiscal year 2026;

22 “(H) \$250,000,000 for fiscal year 2027;

23 “(I) \$275,000,000 for fiscal year 2028;

24 and

25 “(J) \$300,000,000 for fiscal year 2029.”.

1 (d) APPLICATION OF PROVISIONS.—Amounts appro-
 2 priated pursuant to the amendments made by this section
 3 shall be subject to the requirements contained in Public
 4 Law 118–47 for funds for programs authorized under sec-
 5 tions 330 through 340 of the Public Health Service Act
 6 (42 U.S.C. 254b et seq.).

7 (e) CONFORMING AMENDMENTS.—Section
 8 3014(h)(4) of title 18, United States Code, is amended
 9 by striking “and section 3101(d) of the Health Extensions
 10 and Other Matters Act, 2025” and inserting “section
 11 3101(d) of the Health Extensions and Other Matters Act,
 12 2025, and section 401(d) of the Bipartisan Health Care
 13 Act”.

14 **SEC. 402. EXTENSION OF SPECIAL DIABETES PROGRAMS.**

15 (a) EXTENSION OF SPECIAL DIABETES PROGRAMS
 16 FOR TYPE I DIABETES.—Section 330B(b)(2) of the Pub-
 17 lic Health Service Act (42 U.S.C. 254c–2(b)(2)) is amend-
 18 ed—

19 (1) in subparagraph (E), by striking “and” at
 20 the end;

21 (2) in subparagraph (F), by striking the period
 22 at the end and inserting “, and \$110,327,296 for
 23 the period beginning on April 1, 2025, and ending
 24 on September 30, 2025; and”;

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

1 “(G) \$200,000,000 for fiscal year 2026, to
2 remain available until expended.”.

3 (b) EXTENDING FUNDING FOR SPECIAL DIABETES
4 PROGRAMS FOR INDIANS.—Section 330C(c)(2) of the
5 Public Health Service Act (42 U.S.C. 254c-3(c)(2)) is
6 amended—

7 (1) in subparagraph (E), by striking “and” at
8 the end;

9 (2) in subparagraph (F), by striking the period
10 at the end and inserting “, and \$110,327,296 for
11 the period beginning on April 1, 2025, and ending
12 on September 30, 2025; and”; and

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

14 “(G) \$200,000,000 for fiscal year 2026, to
15 remain available until expended.”.

16 **Subtitle B—World Trade Center**
17 **Health Program**

18 **SEC. 411. 9/11 RESPONDER AND SURVIVOR HEALTH FUND-**
19 **ING CORRECTIONS.**

20 (a) IN GENERAL.—Section 3351(a)(2)(A) of the
21 Public Health Service Act (42 U.S.C. 300mm–
22 61(a)(2)(A)) is amended—

23 (1) in clause (x), by striking “; and” and insert-
24 ing a semicolon;

1 (2) by redesignating clause (xi) as clause (xii);

2 and

3 (3) by inserting after clause (x), the following:

4 “(xi) for each of fiscal years 2026
5 through 2040—

6 “(I) the amount determined
7 under this subparagraph for the pre-
8 vious fiscal year multiplied by 1.05;
9 multiplied by

10 “(II) the ratio of—

11 “(aa) the total number of
12 individuals enrolled in the WTC
13 Program on July 1 of such pre-
14 vious fiscal year; to

15 “(bb) the total number of
16 individuals so enrolled on July 1
17 of the fiscal year prior to such
18 previous fiscal year; and”.

19 (b) REPORT TO CONGRESS.—

20 (1) IN GENERAL.—Not later than 3 years after
21 the date of enactment of this Act, the Secretary of
22 Health and Human Services (referred to in this sub-
23 section as the “Secretary”) shall conduct an assess-
24 ment of anticipated budget authority and outlays of
25 the World Trade Center Health Program (referred

1 to in this subsection as the “Program”) through the
2 duration of the Program and submit a report sum-
3 marizing such assessment to—

4 (A) the Speaker and minority leader of the
5 House of Representatives;

6 (B) the majority and minority leaders of
7 the Senate;

8 (C) the Committee on Health, Education,
9 Labor, and Pensions and the Committee on the
10 Budget of the Senate; and

11 (D) the Committee on Energy and Com-
12 merce and the Committee on the Budget of the
13 House of Representatives.

14 (2) INCLUSIONS.—The report required under
15 paragraph (1) shall include—

16 (A) a projection of Program budgetary
17 needs on a per-fiscal year basis through fiscal
18 year 2090;

19 (B) a review of Program modeling for each
20 of fiscal years 2017 through the fiscal year
21 prior to the fiscal year in which the report is
22 issued to assess how anticipated budgetary
23 needs compared to actual expenditures;

1 (C) an assessment of the projected budget
 2 authority and expenditures of the Program
 3 through fiscal year 2090 by comparing—

4 (i) such projected authority and ex-
 5 penditures resulting from application of
 6 section 3351(a)(2)(A) of the Public Health
 7 Service Act (42 U.S.C. 300mm–
 8 61(a)(2)(A)), as amended by subsection
 9 (a); and

10 (ii) such projected authority and ex-
 11 penditures that would result if such section
 12 were amended so that the formula under
 13 clause (xi) of such section, as amended by
 14 subsection (a), were to be extended
 15 through fiscal year 2090; and

16 (D) any recommendations of the Secretary
 17 to make changes to the formula under such sec-
 18 tion 3351(a)(2)(A), as so amended, to fully off-
 19 set anticipated Program expenditures through
 20 fiscal year 2090.

21 (c) TECHNICAL AMENDMENTS.—Title XXXIII of the
 22 Public Health Service Act (42 U.S.C. 300mm et seq.) is
 23 amended—

1 (1) in section 3352(d) (42 U.S.C. 300mm–
 2 62(d)), by striking “Any amounts” and inserting
 3 “Any unobligated amounts”;

4 (2) in section 3353(d) (42 U.S.C. 300mm–
 5 63(d)), by striking “Any amounts” and inserting
 6 “Any unobligated amounts”; and

7 (3) in section 3354(d) (42 U.S.C. 300mm–
 8 64(d)), by striking “Any amounts” and inserting
 9 “Any unobligated amounts”.

10 **TITLE V—SUPPORT ACT** 11 **REAUTHORIZATION**

12 **SEC. 501. SHORT TITLE.**

13 This title may be cited as the “SUPPORT for Pa-
 14 tients and Communities Reauthorization Act of 2025”.

15 **Subtitle A—Prevention**

16 **SEC. 511. PRENATAL AND POSTNATAL HEALTH.**

17 Section 317L(d) of the Public Health Service Act (42
 18 U.S.C. 247b–13(d)) is amended by striking “such sums
 19 as may be necessary for each of the fiscal years 2019
 20 through 2023” and inserting “\$4,250,000 for each of fis-
 21 cal years 2025 through 2029”.

1 **SEC. 512. MONITORING AND EDUCATION REGARDING IN-**
 2 **FECTIONS ASSOCIATED WITH ILLICIT DRUG**
 3 **USE AND OTHER RISK FACTORS.**

4 Section 317N(d) of the Public Health Service Act (42
 5 U.S.C. 247b–15(d)) is amended by striking “fiscal years
 6 2019 through 2023” and inserting “fiscal years 2025
 7 through 2029”.

8 **SEC. 513. PREVENTING OVERDOSES OF CONTROLLED SUB-**
 9 **STANCES.**

10 (a) IN GENERAL.—Section 392A of the Public
 11 Health Service Act (42 U.S.C. 280b–1) is amended—

12 (1) in subsection (a)(2)—

13 (A) in subparagraph (C), by inserting “and
 14 associated risks” before the period at the end;
 15 and

16 (B) in subparagraph (D), by striking
 17 “opioids” and inserting “substances causing
 18 overdose”; and

19 (2) in subsection (b)(2)—

20 (A) in subparagraph (B), by inserting “,
 21 and associated risk factors,” after “such
 22 overdoses”;

23 (B) in subparagraph (C), by striking “cod-
 24 ing” and inserting “monitoring and identi-
 25 fying”;

26 (C) in subparagraph (E)—

1 (i) by inserting a comma after “public
2 health laboratories”; and

3 (ii) by inserting “and other emerging
4 substances related” after “analogues”; and

5 (D) in subparagraph (F), by inserting
6 “and associated risk factors” after “overdoses”.

7 (b) ADDITIONAL GRANTS.—Section 392A(a)(3) of
8 the Public Health Service Act (42 U.S.C. 280b–1(a)(3))
9 is amended—

10 (1) in the matter preceding subparagraph (A),
11 by striking “and Indian Tribes—” and inserting
12 “and Indian Tribes for the following purposes:”;

13 (2) by amending subparagraph (A) to read as
14 follows:

15 “(A) To carry out innovative projects for
16 grantees to detect, identify, and rapidly respond
17 to controlled substance misuse, abuse, and
18 overdoses, and associated risk factors, including
19 changes in patterns of such controlled sub-
20 stance use. Such projects may include the use
21 of innovative, evidence-based strategies for de-
22 tecting such patterns, such as wastewater sur-
23 veillance, if proven to support actionable pre-
24 vention strategies, in a manner consistent with

1 applicable Federal and State privacy laws.”;
 2 and

3 (3) in subparagraph (B), by striking “for any”
 4 and inserting “For any”.

5 (c) AUTHORIZATION OF APPROPRIATIONS.—Section
 6 392A(e) of the Public Health Service Act (42 U.S.C.
 7 280b–1(e)) is amended by striking “\$496,000,000 for
 8 each of fiscal years 2019 through 2023” and inserting
 9 “\$505,579,000 for each of fiscal years 2025 through
 10 2029”.

11 **SEC. 514. SUPPORT FOR INDIVIDUALS AND FAMILIES IM-**
 12 **PACTED BY FETAL ALCOHOL SPECTRUM DIS-**
 13 **ORDER.**

14 (a) IN GENERAL.—Part O of title III of the Public
 15 Health Service Act (42 U.S.C. 280f et seq.) is amended
 16 to read as follows:

17 **“PART O—FETAL ALCOHOL SYNDROME**
 18 **PREVENTION AND SERVICES PROGRAM**
 19 **“SEC. 399H. FETAL ALCOHOL SPECTRUM DISORDERS PRE-**
 20 **VENTION, INTERVENTION, AND SERVICES DE-**
 21 **LIVERY PROGRAM.**

22 “(a) IN GENERAL.—The Secretary shall establish or
 23 continue activities to support a comprehensive fetal alcohol
 24 spectrum disorders (referred to in this section as ‘FASD’)

1 education, prevention, identification, intervention, and
2 services delivery program, which may include—

3 “(1) an education and public awareness pro-
4 gram to support, conduct, and evaluate the effective-
5 ness of—

6 “(A) educational programs targeting
7 health professions schools, social and other sup-
8 portive services, educators and counselors and
9 other service providers in all phases of child-
10 hood development, and other relevant service
11 providers, concerning the prevention, identifica-
12 tion, and provision of services for infants, chil-
13 dren, adolescents and adults with FASD;

14 “(B) strategies to educate school-age chil-
15 dren, including pregnant and high-risk youth,
16 concerning FASD;

17 “(C) public and community awareness pro-
18 grams concerning FASD; and

19 “(D) strategies to coordinate information
20 and services across affected community agen-
21 cies, including agencies providing social services
22 such as foster care, adoption, and social work,
23 agencies providing health services, and agencies
24 involved in education, vocational training and
25 civil and criminal justice;

1 “(2) supporting and conducting research on
2 FASD, as appropriate, including to—

3 “(A) develop appropriate medical diag-
4 nostic methods for identifying FASD; and

5 “(B) develop effective culturally and lin-
6 guistically appropriate evidence-based or evi-
7 dence-informed interventions and appropriate
8 supports for preventing prenatal alcohol expo-
9 sure, which may co-occur with exposure to other
10 substances;

11 “(3) building State and Tribal capacity for the
12 identification, treatment, and support of individuals
13 with FASD and their families, which may include—

14 “(A) utilizing and adapting existing Fed-
15 eral, State, or Tribal programs to include
16 FASD identification and FASD-informed sup-
17 port;

18 “(B) developing and expanding screening
19 and diagnostic capacity for FASD;

20 “(C) developing, implementing, and evalu-
21 ating targeted FASD-informed intervention
22 programs for FASD;

23 “(D) providing training with respect to
24 FASD for professionals across relevant sectors;
25 and

1 “(E) disseminating information about
2 FASD and support services to affected individ-
3 uals and their families; and

4 “(4) an applied research program concerning
5 intervention and prevention to support and conduct
6 service demonstration projects, clinical studies and
7 other research models providing advocacy, edu-
8 cational and vocational training, counseling, medical
9 and mental health, and other supportive services, as
10 well as models that integrate and coordinate such
11 services, that are aimed at the unique challenges fac-
12 ing individuals with Fetal Alcohol Syndrome or
13 Fetal Alcohol Effect and their families.

14 “(b) GRANTS AND TECHNICAL ASSISTANCE.—

15 “(1) IN GENERAL.—The Secretary may award
16 grants, cooperative agreements and contracts and
17 provide technical assistance to eligible entities to
18 carry out subsection (a).

19 “(2) ELIGIBLE ENTITIES.—To be eligible to re-
20 ceive a grant, or enter into a cooperative agreement
21 or contract, under this section, an entity shall—

22 “(A) be a State, Indian Tribe or Tribal or-
23 ganization, local government, scientific or aca-
24 demic institution, or nonprofit organization;
25 and

1 “(B) prepare and submit to the Secretary
 2 an application at such time, in such manner,
 3 and containing such information as the Sec-
 4 retary may require, including a description of
 5 the activities that the entity intends to carry
 6 out using amounts received under this section.

7 “(3) ADDITIONAL APPLICATION CONTENTS.—
 8 The Secretary may require that an eligible entity in-
 9 clude in the application submitted under paragraph
 10 (2)(B)—

11 “(A) a designation of an individual to
 12 serve as a FASD State or Tribal coordinator of
 13 activities such eligible entity proposes to carry
 14 out through a grant, cooperative agreement, or
 15 contract under this section; and

16 “(B) a description of an advisory com-
 17 mittee the entity will establish to provide guid-
 18 ance for the entity on developing and imple-
 19 menting a statewide or Tribal strategic plan to
 20 prevent FASD and provide for the identifica-
 21 tion, treatment, and support of individuals with
 22 FASD and their families.

23 “(c) DEFINITION OF FASD-INFORMED.—For pur-
 24 poses of this section, the term ‘FASD-informed’, with re-
 25 spect to support or an intervention program, means that

1 such support or intervention program uses culturally and
 2 linguistically informed evidence-based or practice-based
 3 interventions and appropriate resources to support an im-
 4 proved quality of life for an individual with FASD and
 5 the family of such individual.

6 **“SEC. 399I. STRENGTHENING CAPACITY AND EDUCATION**
 7 **FOR FETAL ALCOHOL SPECTRUM DIS-**
 8 **ORDERS.**

9 “(a) IN GENERAL.—The Secretary shall award
 10 grants, contracts, or cooperative agreements, as the Sec-
 11 retary determines appropriate, to public or nonprofit pri-
 12 vate entities with demonstrated expertise in the field of
 13 fetal alcohol spectrum disorders (referred to in this section
 14 as ‘FASD’). Such awards shall be for the purposes of
 15 building local, Tribal, State, and nationwide capacities to
 16 prevent the occurrence of FASD by carrying out the pro-
 17 grams described in subsection (b).

18 “(b) PROGRAMS.—An entity receiving an award
 19 under subsection (a) may use such award for the following
 20 purposes:

21 “(1) Developing and supporting public edu-
 22 cation and outreach activities to raise public aware-
 23 ness of the risks associated with alcohol consumption
 24 during pregnancy.

1 “(2) Acting as a clearinghouse for evidence-
2 based resources on FASD prevention, identification,
3 and culturally and linguistically appropriate best
4 practices to help inform systems of care for individ-
5 uals with FASD across their lifespan.

6 “(3) Increasing awareness and understanding
7 of efficacious, evidence-based screening tools and
8 culturally and linguistically appropriate evidence-
9 based intervention services and best practices, which
10 may include improving the capacity for State, Trib-
11 al, and local affiliates.

12 “(4) Providing technical assistance to recipients
13 of grants, cooperative agreements, or contracts
14 under section 399H, as appropriate.

15 “(c) APPLICATION.—To be eligible for a grant, con-
16 tract, or cooperative agreement under this section, an enti-
17 ty shall submit to the Secretary an application at such
18 time, in such manner, and containing such information as
19 the Secretary may require.

20 “(d) SUBCONTRACTING.—A public or private non-
21 profit entity may carry out the following activities required
22 under this section through contracts or cooperative agree-
23 ments with other public and private nonprofit entities with
24 demonstrated expertise in FASD:

25 “(1) Resource development and dissemination.

1 “(2) Intervention services.

2 “(3) Training and technical assistance.

3 **“SEC. 399J. AUTHORIZATION OF APPROPRIATIONS.**

4 “‘There are authorized to be appropriated to carry out
5 this part \$12,500,000 for each of fiscal years 2025
6 through 2029.’”.

7 (b) REPORT.—Not later than 4 years after the date
8 of enactment of this Act, and every year thereafter, the
9 Secretary of Health and Human Services shall prepare
10 and submit to the Committee on Health, Education,
11 Labor, and Pensions of the Senate and the Committee on
12 Energy and Commerce of the House of Representatives
13 a report containing—

14 (1) a review of the activities carried out pursu-
15 ant to sections 399H and 399I of the Public Health
16 Service Act, as amended, to advance public edu-
17 cation and awareness of fetal alcohol spectrum dis-
18 orders (referred to in this section as “FASD”);

19 (2) a description of—

20 (A) the activities carried out pursuant to
21 such sections 399H and 399I to identify, pre-
22 vent, and treat FASD; and

23 (B) methods used to evaluate the outcomes
24 of such activities; and

1 (3) an assessment of activities carried out pur-
 2 suant to such sections 399H and 399I to support in-
 3 dividuals with FASD.

4 **SEC. 515. PROMOTING STATE CHOICE IN PDMP SYSTEMS.**

5 Section 399O(h) of the Public Health Service Act (42
 6 U.S.C. 280g-3(h)) is amended by adding at the end the
 7 following:

8 “(5) PROMOTING STATE CHOICE.—Nothing in
 9 this section shall be construed to authorize the Sec-
 10 retary to require States to use a specific vendor or
 11 a specific interoperability connection other than to
 12 align with nationally recognized, consensus-based
 13 open standards, such as in accordance with sections
 14 3001 and 3004.”.

15 **SEC. 516. FIRST RESPONDER TRAINING PROGRAM.**

16 Section 546 of the Public Health Service Act (42
 17 U.S.C. 290ee-1) is amended—

18 (1) in subsection (a), by striking “tribes and
 19 tribal” and inserting “Tribes and Tribal”;

20 (2) in subsections (a), (c), and (d)—

21 (A) by striking “approved or cleared” each
 22 place it appears and inserting “approved,
 23 cleared, or otherwise legally marketed”; and

24 (B) by striking “opioid” each place it ap-
 25 pears;

1 (3) in subsection (f)—

2 (A) by striking “approved or cleared” each
3 place it appears and inserting “approved,
4 cleared, or otherwise legally marketed”;

5 (B) in paragraph (1), by striking “opioid”;

6 (C) in paragraph (2)—

7 (i) by striking “opioid and heroin”
8 and inserting “opioid, heroin, and other
9 drug”; and

10 (ii) by striking “opioid overdose” and
11 inserting “overdose”; and

12 (D) in paragraph (3), by striking “opioid
13 and heroin”; and

14 (4) in subsection (h), by striking “\$36,000,000
15 for each of fiscal years 2019 through 2023” and in-
16 serting “\$56,000,000 for each of fiscal years 2025
17 through 2029”.

18 **SEC. 517. DONALD J. COHEN NATIONAL CHILD TRAUMATIC**

19 **STRESS INITIATIVE.**

20 (a) **TECHNICAL AMENDMENT.**—The second part G of
21 title V of the Public Health Service Act (42 U.S.C. 290kk
22 et seq.), as added by section 144 of the Community Re-
23 newal Tax Relief Act (Public Law 106–554), is amend-
24 ed—

25 (1) by redesignating such part as part J; and

1 (2) by redesignating sections 581 through 584
2 as sections 596 through 596C, respectively.

3 (b) IN GENERAL.—Section 582 of the Public Health
4 Service Act (42 U.S.C. 290hh–1) is amended—

5 (1) in the section heading, by striking “**VIO-**
6 **LENCE RELATED STRESS**” and inserting “**TRAU-**
7 **MATIC EVENTS**”;

8 (2) in subsection (a)—

9 (A) in the matter preceding paragraph (1),
10 by striking “tribes and tribal” and inserting
11 “Tribes and Tribal”; and

12 (B) in paragraph (2), by inserting “and
13 dissemination” after “the development”;

14 (3) in subsection (b), by inserting “and dissemi-
15 nation” after “the development”;

16 (4) in subsection (d)—

17 (A) by striking “The NCTSI” and insert-
18 ing the following:

19 “(1) COORDINATING CENTER.—The NCTSI”;
20 and

21 (B) by adding at the end the following:

22 “(2) NCTSI GRANTEES.—In carrying out sub-
23 section (a)(2), NCTSI grantees shall develop
24 trainings and other resources, as applicable and ap-
25 propriate, to support implementation of the evi-

1 dence-based practices developed and disseminated
2 under such subsection.”;

3 (5) in subsection (e)—

4 (A) by redesignating paragraphs (1) and
5 (2) as subparagraphs (A) and (B), respectively,
6 and adjusting the margins accordingly;

7 (B) in subparagraph (A), as so redesign-
8 ated, by inserting “and implementation” after
9 “the dissemination”;

10 (C) by striking “The NCTSI” and insert-
11 ing the following:

12 “(1) COORDINATING CENTER.—The NCTSI”;

13 and

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

15 “(2) NCTSI GRANTEES.—NCTSI grantees shall,
16 as appropriate, collaborate with other such grantees,
17 the NCTSI coordinating center, and the Secretary in
18 carrying out subsections (a)(2) and (d)(2).”;

19 (6) by amending subsection (h) to read as fol-
20 lows:

21 “(h) APPLICATION AND EVALUATION.—To be eligible
22 to receive a grant, contract, or cooperative agreement
23 under subsection (a), a public or nonprofit private entity
24 or an Indian Tribe or Tribal organization shall submit to
25 the Secretary an application at such time, in such manner,

1 and containing such information and assurances as the
 2 Secretary may require, including—

3 “(1) a plan for the evaluation of the activities
 4 funded under the grant, contract, or agreement, in-
 5 cluding both process and outcomes evaluation, and
 6 the submission of an evaluation at the end of the
 7 project period; and

8 “(2) a description of how such entity, Indian
 9 Tribe, or Tribal organization will support efforts led
 10 by the Secretary or the NCTSI coordinating center,
 11 as applicable, to evaluate activities carried out under
 12 this section.”; and

13 (7) by amending subsection (j) to read as fol-
 14 lows:

15 “(j) AUTHORIZATION OF APPROPRIATIONS.—There
 16 is authorized to be appropriated to carry out this section—

17 “(1) \$93,887,000 for fiscal year 2025;

18 “(2) \$95,000,000 for fiscal year 2026;

19 “(3) \$97,000,000 for fiscal year 2027;

20 “(4) \$100,000,000 for fiscal year 2028; and

21 “(5) \$100,000,000 for fiscal year 2029.”.

1 **SEC. 518. PROTECTING SUICIDE PREVENTION LIFELINE**
 2 **FROM CYBERSECURITY INCIDENTS.**

3 (a) NATIONAL SUICIDE PREVENTION LIFELINE PRO-
 4 GRAM.—Section 520E–3(b) of the Public Health Service
 5 Act (42 U.S.C. 290bb–36c(b)) is amended—

6 (1) in paragraph (4), by striking “and” at the
 7 end;

8 (2) in paragraph (5), by striking the period at
 9 the end and inserting “; and”; and

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

11 “(6) taking such steps as may be necessary to
 12 ensure the suicide prevention hotline is protected
 13 from cybersecurity incidents and eliminates known
 14 cybersecurity vulnerabilities.”.

15 (b) REPORTING.—Section 520E–3 of the Public
 16 Health Service Act (42 U.S.C. 290bb–36c) is amended—

17 (1) by redesignating subsection (f) as sub-
 18 section (g); and

19 (2) by inserting after subsection (e) the fol-
 20 lowing:

21 “(f) CYBERSECURITY REPORTING.—

22 “(1) NOTIFICATION.—

23 “(A) IN GENERAL.—The program’s net-
 24 work administrator receiving Federal funding
 25 pursuant to subsection (a) shall report to the
 26 Assistant Secretary, in a manner that protects

1 personal privacy, consistent with applicable
2 Federal and State privacy laws—

3 “(i) any identified cybersecurity
4 vulnerabilities to the program within a rea-
5 sonable amount of time after identification
6 of such a vulnerability; and

7 “(ii) any identified cybersecurity inci-
8 dents to the program within a reasonable
9 amount of time after identification of such
10 incident.

11 “(B) LOCAL AND REGIONAL CRISIS CEN-
12 TERS.—Local and regional crisis centers par-
13 ticipating in the program shall report to the
14 program’s network administrator identified
15 under subparagraph (A), in a manner that pro-
16 tects personal privacy, consistent with applica-
17 ble Federal and State privacy laws—

18 “(i) any identified cybersecurity
19 vulnerabilities to the program within a rea-
20 sonable amount of time after identification
21 of such vulnerability; and

22 “(ii) any identified cybersecurity inci-
23 dents to the program within a reasonable
24 amount of time after identification of such
25 incident.

1 “(2) NOTIFICATION.—If the program’s network
2 administrator receiving funding pursuant to sub-
3 section (a) discovers, or is informed by a local or re-
4 gional crisis center pursuant to paragraph (1)(B) of,
5 a cybersecurity vulnerability or incident, within a
6 reasonable amount of time after such discovery or
7 receipt of information, such entity shall report the
8 vulnerability or incident to the Assistant Secretary.

9 “(3) CLARIFICATION.—

10 “(A) OVERSIGHT.—

11 “(i) LOCAL AND REGIONAL CRISIS
12 CENTERS.—Except as provided in clause
13 (ii), local and regional crisis centers par-
14 ticipating in the program shall oversee all
15 technology each center employs in the pro-
16 vision of services as a participant in the
17 program.

18 “(ii) NETWORK ADMINISTRATOR.—
19 The program’s network administrator re-
20 ceiving Federal funding pursuant to sub-
21 section (a) shall oversee the technology
22 each crisis center employs in the provision
23 of services as a participant in the program
24 if such oversight responsibilities are estab-

1 lished in the applicable network participa-
2 tion agreement.

3 “(B) SUPPLEMENT, NOT SUPPLANT.—The
4 cybersecurity incident reporting requirements
5 under this subsection shall supplement, and not
6 supplant, cybersecurity incident reporting re-
7 quirements under other provisions of applicable
8 Federal law that are in effect on the date of the
9 enactment of the SUPPORT for Patients and
10 Communities Reauthorization Act of 2025.”.

11 (c) STUDY.—Not later than 180 days after the date
12 of the enactment of this Act, the Comptroller General of
13 the United States shall—

14 (1) conduct and complete a study that evaluates
15 cybersecurity risks and vulnerabilities associated
16 with the 9–8–8 National Suicide Prevention Lifeline;
17 and

18 (2) submit a report on the findings of such
19 study to the Committee on Health, Education,
20 Labor, and Pensions of the Senate and the Com-
21 mittee on Energy and Commerce of the House of
22 Representatives.

1 **SEC. 519. BRUCE’S LAW.**

2 (a) YOUTH PREVENTION AND RECOVERY.—Section
3 7102(c) of the SUPPORT for Patients and Communities
4 Act (42 U.S.C. 290bb–7a(c)) is amended—

5 (1) in paragraph (3)(A)(i), by inserting “,
6 which may include strategies to increase education
7 and awareness of the potency and dangers of syn-
8 thetic opioids (including drugs contaminated with
9 fentanyl) and, as appropriate, other emerging drug
10 use or misuse issues” before the semicolon; and

11 (2) in paragraph (4)(A), by inserting “and
12 strategies to increase education and awareness of
13 the potency and dangers of synthetic opioids (includ-
14 ing drugs contaminated with fentanyl) and, as ap-
15 propriate, emerging drug use or misuse issues” be-
16 fore the semicolon.

17 (b) INTERDEPARTMENTAL SUBSTANCE USE DIS-
18 ORDERS COORDINATING COMMITTEE.—Section 7022 of
19 the SUPPORT for Patients and Communities Act (42
20 U.S.C. 290aa note) is amended—

21 (1) by striking subsection (g) and inserting the
22 following:

23 “(g) WORKING GROUPS.—

24 “(1) IN GENERAL.—The Committee may estab-
25 lish working groups for purposes of carrying out the
26 duties described in subsection (e). Any such working

1 group shall be composed of members of the Com-
2 mittee (or the designees of such members) and may
3 hold such meetings as are necessary to carry out the
4 duties delegated to the working group.

5 “(2) ADDITIONAL FEDERAL INTERAGENCY
6 WORK GROUP ON FENTANYL CONTAMINATION OF IL-
7 LEGAL DRUGS.—

8 “(A) ESTABLISHMENT.—The Secretary,
9 acting through the Committee, shall establish a
10 Federal Interagency Work Group on Fentanyl
11 Contamination of Illegal Drugs (referred to in
12 this paragraph as the ‘Work Group’) consisting
13 of representatives from relevant Federal depart-
14 ments and agencies on the Committee.

15 “(B) CONSULTATION.—The Work Group
16 shall consult with relevant stakeholders and
17 subject matter experts, including—

18 “(i) State, Tribal, and local subject
19 matter experts in reducing, preventing, and
20 responding to drug overdose caused by
21 fentanyl-contamination of illicit drugs; and

22 “(ii) family members of both adults
23 and youth who have overdosed by fentanyl-
24 contaminated illicit drugs.

25 “(C) DUTIES.—The Work Group shall—

1 “(i) examine Federal efforts to reduce
2 and prevent drug overdose by fentanyl-con-
3 taminated illicit drugs;

4 “(ii) identify strategies to improve
5 State, Tribal, and local responses to over-
6 dose by fentanyl-contaminated illicit drugs;

7 “(iii) coordinate with the Secretary, as
8 appropriate, in carrying out activities to
9 raise public awareness of synthetic opioids
10 and other emerging drug use and misuse
11 issues;

12 “(iv) make recommendations to Con-
13 gress for improving Federal programs, in-
14 cluding with respect to the coordination of
15 efforts across such programs; and

16 “(v) make recommendations for edu-
17 cating youth on the potency and dangers of
18 drugs contaminated by fentanyl.

19 “(D) ANNUAL REPORT TO SECRETARY.—
20 The Work Group shall annually prepare and
21 submit to the Secretary, the Committee on
22 Health, Education, Labor, and Pensions of the
23 Senate, and the Committee on Energy and
24 Commerce and the Committee on Education
25 and the Workforce of the House of Representa-

1 tives, a report on the activities carried out by
 2 the Work Group under subparagraph (C), in-
 3 cluding recommendations to reduce and prevent
 4 drug overdose by fentanyl contamination of ille-
 5 gal drugs, in all populations, and specifically
 6 among youth at risk for substance misuse.”;
 7 and

8 (2) by striking subsection (i) and inserting the
 9 following:

10 “(i) SUNSET.—The Committee shall
 11 terminate on September 30, 2029.”.

12 **SEC. 520. GUIDANCE ON AT-HOME DRUG DISPOSAL SYS-**
 13 **TEMS.**

14 (a) IN GENERAL.—Not later than one year after the
 15 date of enactment of this Act, the Secretary of Health and
 16 Human Services, in consultation with the Administrator
 17 of the Drug Enforcement Administration, shall publish
 18 guidance to facilitate the use of at-home safe disposal sys-
 19 tems for applicable drugs.

20 (b) CONTENTS.—The guidance under subsection (a)
 21 shall include—

22 (1) recommended standards for effective at-
 23 home drug disposal systems to meet applicable re-
 24 quirements enforced by the Food and Drug Adminis-
 25 tration;

1 (2) recommended information to include as in-
2 structions for use to disseminate with at-home drug
3 disposal systems;

4 (3) best practices and educational tools to sup-
5 port the use of an at-home drug disposal system, as
6 appropriate; and

7 (4) recommended use of licensed health pro-
8 viders for the dissemination of education, instruc-
9 tion, and at-home drug disposal systems, as appro-
10 prium.

11 **SEC. 521. ASSESSMENT OF OPIOID DRUGS AND ACTIONS.**

12 (a) IN GENERAL.—Not later than one year after the
13 date of enactment of this Act, the Secretary of Health and
14 Human Services (referred to in this section as the “Sec-
15 retary”) shall publish on the website of the Food and
16 Drug Administration (referred to in this section as the
17 “FDA”) a report that outlines a plan for assessing opioid
18 analgesic drugs that are approved under section 505 of
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 355) that addresses the public health effects of such opioid
21 analgesic drugs as part of the benefit-risk assessment and
22 the activities of the FDA that relate to facilitating the de-
23 velopment of nonaddictive medical products intended to
24 treat pain or addiction. Such report shall include—

1 (1) an update on the actions taken by the FDA
2 to consider the effectiveness, safety, benefit-risk pro-
3 file, and use of approved opioid analgesic drugs;

4 (2) a timeline for an assessment of the potential
5 need, as appropriate, for labeling changes, revised or
6 additional postmarketing requirements, enforcement
7 actions, or withdrawals for opioid analgesic drugs;

8 (3) an overview of the steps that the FDA has
9 taken to support the development and approval of
10 nonaddictive medical products intended to treat pain
11 or addiction, and actions planned to further support
12 the development and approval of such products; and

13 (4) an overview of the consideration by the
14 FDA of clinical trial methodologies for analgesic
15 drugs, including the enriched enrollment randomized
16 withdrawal methodology, and the benefits and draw-
17 backs associated with different trial methodologies
18 for such drugs, incorporating any public input re-
19 ceived under subsection (b).

20 (b) PUBLIC INPUT.—In carrying out subsection (a),
21 the Secretary shall provide an opportunity for public input
22 concerning the regulation by the FDA of opioid analgesic
23 drugs, including scientific evidence that relates to condi-
24 tions of use, safety, or benefit-risk assessment (including

1 consideration of the public health effects) of such opioid
 2 analgesic drugs.

3 **SEC. 522. GRANT PROGRAM FOR STATE AND TRIBAL RE-**
 4 **SPONSE TO OPIOID USE DISORDERS.**

5 The activities carried out pursuant to section
 6 1003(b)(4)(A) of the 21st Century Cures Act (42 U.S.C.
 7 290ee–3a(b)(4)(A)) may include facilitating access to
 8 products used to prevent overdose deaths by detecting the
 9 presence of one or more substances, such as fentanyl and
 10 xylazine test strips, to the extent the purchase and posses-
 11 sion of such products is consistent with Federal and State
 12 law.

13 **Subtitle B—Treatment**

14 **SEC. 531. RESIDENTIAL TREATMENT PROGRAM FOR PREG-**
 15 **NANT AND POSTPARTUM WOMEN.**

16 Section 508 of the Public Health Service Act (42
 17 U.S.C. 290bb–1) is amended—

18 (1) in subsection (d)(11)(C), by striking “pro-
 19 viding health services” and inserting “providing
 20 health care services”;

21 (2) in subsection (g)—

22 (A) by inserting “a plan describing” after
 23 “will provide”; and

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

25 “Such plan may include a description of how

1 such applicant will target outreach to women
2 disproportionately impacted by maternal sub-
3 stance use disorder.”; and

4 (3) in subsection (s), by striking “\$29,931,000
5 for each of fiscal years 2019 through 2023” and in-
6 serting “\$38,931,000 for each of fiscal years 2025
7 through 2029”.

8 **SEC. 532. IMPROVING ACCESS TO ADDICTION MEDICINE**
9 **PROVIDERS.**

10 Section 597 of the Public Health Service Act (42
11 U.S.C. 290ll) is amended—

12 (1) in subsection (a)(1), by inserting “diag-
13 nosis,” after “related to”; and

14 (2) in subsection (b), by inserting “addiction
15 medicine,” after “psychiatry,”.

16 **SEC. 533. MENTAL AND BEHAVIORAL HEALTH EDUCATION**
17 **AND TRAINING GRANTS.**

18 Section 756(f) of the Public Health Service Act (42
19 U.S.C. 294e–1(f)) is amended by striking “fiscal years
20 2023 through 2027” and inserting “fiscal years 2025
21 through 2029”.

22 **SEC. 534. LOAN REPAYMENT PROGRAM FOR SUBSTANCE**
23 **USE DISORDER TREATMENT WORKFORCE.**

24 Section 781(j) of the Public Health Service Act (42
25 U.S.C. 295h(j)) is amended by striking “\$25,000,000 for

1 each of fiscal years 2019 through 2023” and inserting
 2 “\$40,000,000 for each of fiscal years 2025 through
 3 2029”.

4 **SEC. 535. DEVELOPMENT AND DISSEMINATION OF MODEL**
 5 **TRAINING PROGRAMS FOR SUBSTANCE USE**
 6 **DISORDER PATIENT RECORDS.**

7 Section 7053 of the SUPPORT for Patients and
 8 Communities Act (42 U.S.C. 290dd–2 note) is amended
 9 by striking subsection (e).

10 **SEC. 536. TASK FORCE ON BEST PRACTICES FOR TRAUMA-**
 11 **INFORMED IDENTIFICATION, REFERRAL, AND**
 12 **SUPPORT.**

13 Section 7132 of the SUPPORT for Patients and
 14 Communities Act (Public Law 115–271; 132 Stat. 4046)
 15 is amended—

16 (1) in subsection (b)(1)—

17 (A) by redesignating subparagraph (CC) as
 18 subparagraph (DD); and

19 (B) by inserting after subparagraph (BB)
 20 the following:

21 “(CC) The Administration for Community
 22 Living.”;

23 (2) in subsection (d)(1), in the matter pre-
 24 ceding subparagraph (A), by inserting “, develop-

1 mental disability service providers” before “, individ-
 2 uals who are”; and

3 (3) in subsection (i), by striking “2023” and in-
 4 sserting “2029”.

5 **SEC. 537. GRANTS TO ENHANCE ACCESS TO SUBSTANCE**
 6 **USE DISORDER TREATMENT.**

7 Section 3203 of the SUPPORT for Patients and
 8 Communities Act (21 U.S.C. 823 note) is amended—

9 (1) by striking subsection (b); and

10 (2) by striking “(a) IN GENERAL.—The Sec-
 11 retary” and inserting the following: “The Sec-
 12 retary”.

13 **SEC. 538. STATE GUIDANCE RELATED TO INDIVIDUALS**
 14 **WITH SERIOUS MENTAL ILLNESS AND CHIL-**
 15 **DREN WITH SERIOUS EMOTIONAL DISTURB-**
 16 **ANCE.**

17 (a) REVIEW OF USE OF CERTAIN FUNDING.—Not
 18 later than 1 year after the date of enactment of this Act,
 19 the Secretary of Health and Human Services (referred to
 20 in this section as the “Secretary”), acting through the As-
 21 sistant Secretary for Mental Health and Substance Use,
 22 shall conduct a review of State use of funds made available
 23 under the Community Mental Health Services Block
 24 Grant program under subpart I of part B of title XIX
 25 of the Public Health Service Act (42 U.S.C. 300x et seq.)

1 (referred to in this section as the “block grant program”)
2 for first episode psychosis activities. Such review shall con-
3 sider the following:

4 (1) How States use funds for evidence-based
5 treatments and services according to the standard of
6 care for individuals with early serious mental illness
7 and children with a serious emotional disturbance.

8 (2) The percentages of the State funding under
9 the block grant program expended on early serious
10 mental illness and first episode psychosis, and the
11 number of individuals served under such funds.

12 (b) REPORT AND GUIDANCE.—

13 (1) REPORT.—Not later than 180 days after
14 the completion of the review under subsection (a),
15 the Secretary shall submit to the Committee on
16 Health, Education, Labor, and Pensions and the
17 Committee on Appropriations of the Senate and the
18 Committee on Energy and Commerce and the Com-
19 mittee on Appropriations of the House of Represent-
20 atives a report describing—

21 (A) the findings of the review under sub-
22 section (a); and

23 (B) any recommendations for changes to
24 the block grant program that would facilitate
25 improved outcomes for individuals with serious

1 mental illness and children with serious emo-
2 tional disturbance.

3 (2) GUIDANCE.—Not later than 1 year after
4 the date on which the report is submitted under
5 paragraph (1), the Secretary shall update the guid-
6 ance provided to States under the block grant pro-
7 gram on coordinated specialty care and other evi-
8 dence-based mental health care services for individ-
9 uals with serious mental illness and children with a
10 serious emotional disturbance, based on the findings
11 and recommendations of such report.

12 **SEC. 539. REVIEWING THE SCHEDULING OF APPROVED**
13 **PRODUCTS CONTAINING A COMBINATION OF**
14 **BUPRENORPHINE AND NALOXONE.**

15 (a) SECRETARY OF HHS.—The Secretary of Health
16 and Human Services shall, consistent with the require-
17 ments and procedures set forth in sections 201 and 202
18 of the Controlled Substances Act (21 U.S.C. 811, 812)—

19 (1) review the relevant data pertaining to the
20 scheduling of products containing a combination of
21 buprenorphine and naloxone that have been ap-
22 proved under section 505 of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 355); and

1 (2) if appropriate, request that the Attorney
2 General initiate rulemaking proceedings to revise the
3 schedules accordingly with respect to such products.

4 (b) ATTORNEY GENERAL.—The Attorney General
5 shall review any request made by the Secretary of Health
6 and Human Services under subsection (a)(2) and deter-
7 mine whether to initiate proceedings to revise the sched-
8 ules in accordance with the criteria set forth in sections
9 201 and 202 of the Controlled Substances Act (21 U.S.C.
10 811, 812).

11 **Subtitle C—Recovery**

12 **SEC. 541. BUILDING COMMUNITIES OF RECOVERY.**

13 Section 547(f) of the Public Health Service Act (42
14 U.S.C. 290ee–2(f)) is amended by striking “\$5,000,000
15 for each of fiscal years 2019 through 2023” and inserting
16 “\$16,000,000 for each of fiscal years 2025 through
17 2029”.

18 **SEC. 542. PEER SUPPORT TECHNICAL ASSISTANCE CEN-** 19 **TER.**

20 Section 547A of the Public Health Service Act (42
21 U.S.C. 290ee–2a) is amended—

22 (1) in subsection (b)(4), by striking “building;
23 and” and inserting the following: “building, such
24 as—

1 “(A) professional development of peer sup-
2 port specialists; and

3 “(B) making recovery support services
4 available in nonclinical settings; and”;

5 (2) by redesignating subsections (d) and (e) as
6 subsections (e) and (f), respectively;

7 (3) by inserting after subsection (c) the fol-
8 lowing:

9 “(d) REGIONAL CENTERS.—

10 “(1) IN GENERAL.—The Secretary may estab-
11 lish one regional technical assistance center (referred
12 to in this subsection as the ‘Regional Center’), with
13 existing resources, to assist the Center in carrying
14 out activities described in subsection (b) within the
15 geographic region of such Regional Center in a man-
16 ner that is tailored to the needs of such region.

17 “(2) EVALUATION.—Not later than 4 years
18 after the date of enactment of the SUPPORT for
19 Patients and Communities Reauthorization Act of
20 2025, the Secretary shall evaluate the activities of
21 the Regional Center and submit to the Committee
22 on Health, Education, Labor, and Pensions of the
23 Senate and the Committee on Energy and Com-
24 merce of the House of Representatives a report on
25 the findings of such evaluation, including—

1 “(A) a description of the distinct roles and
 2 responsibilities of the Regional Center and the
 3 Center;

4 “(B) available information relating to the
 5 outcomes of the Regional Center under this
 6 subsection, such as any impact on the oper-
 7 ations and efficiency of the Center relating to
 8 requests for technical assistance and support
 9 within the region of such Regional Center;

10 “(C) a description of any gaps or areas of
 11 duplication relating to the activities of the Re-
 12 gional Center and the Center within such re-
 13 gion; and

14 “(D) recommendations relating to the
 15 modification, expansion, or termination of the
 16 Regional Center under this subsection.

17 “(3) TERMINATION.—This subsection shall ter-
 18 minate on September 30, 2029.”; and

19 (4) in subsection (f), as so redesignated, by
 20 striking “\$1,000,000 for each of fiscal years 2019
 21 through 2023” and inserting “\$2,000,000 for each
 22 of fiscal years 2025 through 2029”.

23 **SEC. 543. COMPREHENSIVE OPIOID RECOVERY CENTERS.**

24 Section 552 of the Public Health Service Act (42
 25 U.S.C. 290ee–7) is amended—

1 (1) in subsection (d)(2)—

2 (A) in the matter preceding subparagraph
3 (A), by striking “and in such manner” and in-
4 serting “, in such manner, and containing such
5 information and assurances, including relevant
6 documentation,”; and

7 (B) in subparagraph (A), by striking “is
8 capable of coordinating with other entities to
9 carry out” and inserting “has the demonstrated
10 capability to carry out, through referral or con-
11 tractual arrangements”;

12 (2) in subsection (h)—

13 (A) by redesignating paragraphs (1)
14 through (4) as subparagraphs (A) through (D),
15 respectively, and adjusting the margins accord-
16 ingly;

17 (B) by striking “With respect to” and in-
18 serting the following:

19 “(1) IN GENERAL.—With respect to”; and

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

21 “(2) ADDITIONAL REPORTING FOR CERTAIN EL-
22 IGIBLE ENTITIES.—An entity carrying out activities
23 described in subsection (g) through referral or con-
24 tractual arrangements shall include in the submis-
25 sions required under paragraph (1) information re-

1 lated to the status of such referrals or contractual
 2 arrangements, including an assessment of whether
 3 such referrals or contractual arrangements are sup-
 4 porting the ability of such entity to carry out such
 5 activities.”; and

6 (3) in subsection (j), by striking “2019 through
 7 2023” and inserting “2025 through 2029”.

8 **SEC. 544. YOUTH PREVENTION AND RECOVERY.**

9 Section 7102(c) of the SUPPORT for Patients and
 10 Communities Act (42 U.S.C. 290bb–7a(c)) (as amended
 11 by section 110(a)) is amended—

12 (1) in paragraph (2)—

13 (A) in subparagraph (A)—

14 (i) in clause (i)—

15 (I) by inserting “, or a consor-
 16 tium of local educational agencies,”
 17 after “a local educational agency”;
 18 and

19 (II) by striking “high schools”
 20 and inserting “secondary schools”;
 21 and

22 (ii) in clause (vi), by striking “tribe,
 23 or tribal” and inserting “Tribe, or Tribal”;

24 (B) by amending subparagraph (E) to read
 25 as follows:

1 “(E) INDIAN TRIBE; TRIBAL ORGANIZA-
 2 TION.—The terms ‘Indian Tribe’ and ‘Tribal
 3 organization’ have the meanings given such
 4 terms in section 4 of the Indian Self-Deter-
 5 mination and Education Assistance Act (25
 6 U.S.C. 5304).”;

7 (C) by redesignating subparagraph (K) as
 8 subparagraph (L); and

9 (D) by inserting after subparagraph (J)
 10 the following:

11 “(K) SECONDARY SCHOOL.—The term
 12 ‘secondary school’ has the meaning given such
 13 term in section 8101 of the Elementary and
 14 Secondary Education Act of 1965 (20 U.S.C.
 15 7801).”;

16 (2) in paragraph (3)(A), in the matter pre-
 17 ceding clause (i)—

18 (A) by striking “and abuse”; and

19 (B) by inserting “at increased risk for sub-
 20 stance misuse” after “specific populations”;

21 (3) in paragraph (4)—

22 (A) in the matter preceding subparagraph
 23 (A), by striking “Indian tribes” and inserting
 24 “Indian Tribes”;

1 (B) in subparagraph (A), by striking “and
2 abuse”; and

3 (C) in subparagraph (B), by striking “peer
4 mentoring” and inserting “peer-to-peer sup-
5 port”;

6 (4) in paragraph (5), by striking “tribal” and
7 inserting “Tribal”;

8 (5) in paragraph (6)(A)—

9 (A) in clause (iv), by striking “; and” and
10 inserting a semicolon; and

11 (B) by adding at the end the following:

12 “(vi) a plan to sustain the activities
13 carried out under the grant program, after
14 the grant program has ended; and”;

15 (6) in paragraph (8), by striking “2022” and
16 inserting “2027”; and

17 (7) by amending paragraph (9) to read as fol-
18 lows:

19 “(9) AUTHORIZATION OF APPROPRIATIONS.—
20 To carry out this subsection, there are authorized to
21 be appropriated—

22 “(A) \$10,000,000 for fiscal year 2025;

23 “(B) \$12,000,000 for fiscal year 2026;

24 “(C) \$13,000,000 for fiscal year 2027;

1 “(D) \$14,000,000 for fiscal year 2028;

2 and

3 “(E) \$15,000,000 for fiscal year 2029.”.

4 **SEC. 545. CAREER ACT.**

5 (a) IN GENERAL.—Section 7183 of the SUPPORT
6 for Patients and Communities Act (42 U.S.C. 290ee–8)
7 is amended—

8 (1) in the section heading, by inserting “;

9 **TREATMENT, RECOVERY, AND WORKFORCE**

10 **SUPPORT GRANTS”** after “**CAREER ACT**”;

11 (2) in subsection (b), by inserting “each” before
12 “for a period”;

13 (3) in subsection (c)—

14 (A) in paragraph (1), by striking “the
15 rates described in paragraph (2)” and inserting
16 “the average rates for calendar years 2018
17 through 2022 described in paragraph (2)”; and

18 (B) by amending paragraph (2) to read as
19 follows:

20 “(2) RATES.—The rates described in this para-
21 graph are the following:

22 “(A) The highest age-adjusted average
23 rates of drug overdose deaths for calendar years
24 2018 through 2022 based on data from the
25 Centers for Disease Control and Prevention, in-

cluding, if necessary, provisional data for calendar year 2022.

“(B) The highest average rates of unemployment for calendar years 2018 through 2022 based on data provided by the Bureau of Labor Statistics.

“(C) The lowest average labor force participation rates for calendar years 2018 through 2022 based on data provided by the Bureau of Labor Statistics.”;

(4) in subsection (g)—

(A) in each of paragraphs (1) and (3), by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and adjusting the margins accordingly;

(B) by redesignating paragraphs (1) through (3) as subparagraphs (A) through (C), respectively, and adjusting the margins accordingly;

(C) in the matter preceding subparagraph (A) (as so redesignated), by striking “An entity” and inserting the following:

“(1) IN GENERAL.—An entity”; and

(D) by adding at the end the following:

1 “(2) TRANSPORTATION SERVICES.—An entity
 2 receiving a grant under this section may use not
 3 more than 5 percent of the funds for providing
 4 transportation for individuals to participate in an ac-
 5 tivity supported by a grant under this section, which
 6 transportation shall be to or from a place of work
 7 or a place where the individual is receiving voca-
 8 tional education or job training services or receiving
 9 services directly linked to treatment of or recovery
 10 from a substance use disorder.

11 “(3) LIMITATION.—The Secretary may not re-
 12 quire an entity to, or give priority to an entity that
 13 plans to, use the funds of a grant under this section
 14 for activities that are not specified in this sub-
 15 section.”;

16 (5) in subsection (i)(2), by inserting “, which
 17 shall include employment and earnings outcomes de-
 18 scribed in subclauses (I) and (III) of section
 19 116(b)(2)(A)(i) of the Workforce Innovation and
 20 Opportunity Act (29 U.S.C. 3141(b)(2)(A)(i)) with
 21 respect to the participation of such individuals with
 22 a substance use disorder in programs and activities
 23 funded by the grant under this section” after “sub-
 24 section (g)”;

25 (6) in subsection (j)—

(A) in paragraph (1), by inserting “for grants awarded prior to the date of enactment of the SUPPORT for Patients and Communities Reauthorization Act of 2025” after “grant period under this section”; and

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking “2 years after submitting the preliminary report required under paragraph (1)” and inserting “September 30, 2029”; and

(ii) in subparagraph (A), by striking “(g)(3)” and inserting “(g)(1)(C)”; and

(7) in subsection (k), by striking “\$5,000,000 for each of fiscal years 2019 through 2023” and inserting “\$12,000,000 for each of fiscal years 2025 through 2029”.

(b) REAUTHORIZATION OF THE CAREER ACT; RECOVERY HOUSING PILOT PROGRAM.—

(1) IN GENERAL.—Section 8071 of the SUPPORT for Patients and Communities Act (42 U.S.C. 5301 note; Public Law 115–271) is amended—

1 (A) by striking the section heading and in-
2 serting “**CAREER ACT; RECOVERY HOUSING**
3 **PILOT PROGRAM**”;

4 (B) in subsection (a), by striking “through
5 2023” and inserting “through 2029”;

6 (C) in subsection (b)—

7 (i) in paragraph (1), by striking “not
8 later than 60 days after the date of enact-
9 ment of this Act” and inserting “not later
10 than 60 days after the date of enactment
11 of the SUPPORT for Patients and Com-
12 munities Reauthorization Act of 2025”;
13 and

14 (ii) in paragraph (2)(B)(i)—

15 (I) in subclause (I)—

16 (aa) by striking “for cal-
17 endar years 2013 through 2017”;
18 and

19 (bb) by inserting “for cal-
20 endar years 2018 through 2022”
21 after “rates of unemployment”;

22 (II) in subclause (II)—

23 (aa) by striking “for cal-
24 endar years 2013 through 2017”;
25 and

1 (bb) by inserting “for cal-
 2 endar years 2018 through 2022”
 3 after “participation rates”; and
 4 (III) by striking subclause (III)
 5 and inserting the following:

6 “(III) The highest age-adjusted
 7 average rates of drug overdose deaths
 8 for calendar years 2018 through 2022
 9 based on data from the Centers for
 10 Disease Control and Prevention, in-
 11 cluding, if necessary, provisional data
 12 for calendar year 2022.”; and

13 (D) in subsection (f), by striking “For the
 14 2-year period following the date of enactment of
 15 this Act, the” and inserting “The”.

16 (2) CONFORMING AMENDMENT.—Subtitle F of
 17 title VIII of the SUPPORT for Patients and Com-
 18 munities Act (Public Law 115–271; 132 Stat. 4095)
 19 is amended by striking the subtitle heading and in-
 20 serting the following: “**Subtitle F—CAREER**
 21 **Act; Recovery Housing Pilot Program**” .

22 (c) CLERICAL AMENDMENTS.—The table of contents
 23 in section 1(b) of the SUPPORT for Patients and Com-
 24 munities Act (Public Law 115–271; 132 Stat. 3894) is
 25 amended—

1 (1) by striking the item relating to section 7183
 2 and inserting the following:

“Sec. 7183. CAREER Act; treatment, recovery, and workforce support grants.”;

3 (2) by striking the item relating to subtitle F
 4 of title VIII and inserting the following:

“Subtitle F—CAREER Act; Recovery Housing Pilot Program”; and

5 (3) by striking the item relating to section 8071
 6 and inserting the following:

“Sec. 8071. CAREER Act; Recovery Housing Pilot Program.”.

7 **SEC. 546. ADDRESSING ECONOMIC AND WORKFORCE IM-**
 8 **PACTS OF THE OPIOID CRISIS.**

9 Section 8041(g)(1) of the SUPPORT for Patients
 10 and Communities Act (29 U.S.C. 3225a(g)(1)) is amended
 11 by striking “2023” and inserting “2029”.

12 **Subtitle D—Miscellaneous Matters**

13 **SEC. 551. DELIVERY OF A CONTROLLED SUBSTANCE BY A**
 14 **PHARMACY TO A PRESCRIBING PRACTI-**
 15 **TIONER.**

16 Section 309A(a) of the Controlled Substances Act
 17 (21 U.S.C. 829a(a)) is amended by striking paragraph (2)
 18 and inserting the following:

19 “(2) the controlled substance is a drug in
 20 schedule III, IV, or V to be administered—

1 “(A) by injection or implantation for the
2 purpose of maintenance or detoxification treat-
3 ment; or

4 “(B) subject to a risk evaluation and miti-
5 gation strategy pursuant to section 505–1 of
6 the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 355–1) that includes elements to assure
8 safe use of the drug described in subsection
9 (f)(3)(E) of such section, including a require-
10 ment for post-administration monitoring by a
11 health care provider.”.

12 **SEC. 552. TECHNICAL CORRECTION ON CONTROLLED SUB-**
13 **STANCES DISPENSING.**

14 Effective as if included in the enactment of Public
15 Law 117–328—

16 (1) section 1252(a) of division FF of Public
17 Law 117–328 (136 Stat. 5681) is amended, in the
18 matter being inserted into section 302(e) of the Con-
19 trolled Substances Act, by striking “303(g)” and in-
20 serting “303(h)”;

21 (2) section 1262 of division FF of Public Law
22 117–328 (136 Stat. 5681) is amended—

23 (A) in subsection (a)—

1 (i) in the matter preceding paragraph
 2 (1), by striking “303(g)” and inserting
 3 “303(h)”;

4 (ii) in the matter being stricken by
 5 subsection (a)(2), by striking “(g)(1)” and
 6 inserting “(h)(1)”;

7 (iii) in the matter being inserted by
 8 subsection (a)(2), by striking “(g) Practi-
 9 tioners” and inserting “(h) Practitioners”;
 10 and

11 (B) in subsection (b)—

12 (i) in the matter being stricken by
 13 paragraph (1), by striking “303(g)(1)”
 14 and inserting “303(h)(1)”;

15 (ii) in the matter being inserted by
 16 paragraph (1), by striking “303(g)” and
 17 inserting “303(h)”;

18 (iii) in the matter being stricken by
 19 paragraph (2)(A), by striking “303(g)(2)”
 20 and inserting “303(h)(2)”;

21 (iv) in the matter being stricken by
 22 paragraph (3), by striking “303(g)(2)(B)”
 23 and inserting “303(h)(2)(B)”;

1 (v) in the matter being stricken by
 2 paragraph (5), by striking “303(g)” and
 3 inserting “303(h)”; and

4 (vi) in the matter being stricken by
 5 paragraph (6), by striking “303(g)” and
 6 inserting “303(h)”; and

7 (3) section 1263(b) of division FF of Public
 8 Law 117–328 (136 Stat. 5685) is amended—

9 (A) by striking “303(g)(2)” and inserting
 10 “303(h)(2)”; and

11 (B) by striking “(21 U.S.C. 823(g)(2))”
 12 and inserting “(21 U.S.C. 823(h)(2))”.

13 **SEC. 553. REQUIRED TRAINING FOR PRESCRIBERS OF CON-**
 14 **TROLLED SUBSTANCES.**

15 (a) IN GENERAL.—Section 303 of the Controlled
 16 Substances Act (21 U.S.C. 823) is amended—

17 (1) by redesignating the second subsection des-
 18 ignated as subsection (l) as subsection (m); and

19 (2) in subsection (m)(1), as so redesignated—

20 (A) in subparagraph (A)—

21 (i) in clause (iv)—

22 (I) in subclause (I)—

23 (aa) by inserting “the Amer-
 24 ican Academy of Family Physi-
 25 cians, the American Podiatric

1 Medical Association, the Acad-
 2 emy of General Dentistry, the
 3 American Optometric Associa-
 4 tion,” before “or any other orga-
 5 nization”;

6 (bb) by striking “or the
 7 Commission” and inserting “the
 8 Commission”; and

9 (cc) by inserting “, or the
 10 Council on Podiatric Medical
 11 Education” before the semicolon
 12 at the end; and

13 (II) in subclause (III), by insert-
 14 ing “or the American Academy of
 15 Family Physicians” after “Associa-
 16 tion”; and

17 (ii) in clause (v), in the matter pre-
 18 ceding subclause (I)—

19 (I) by striking “osteopathic medi-
 20 cine, dental surgery” and inserting
 21 “osteopathic medicine, podiatric medi-
 22 cine, dental surgery”; and

23 (II) by striking “or dental medi-
 24 cine curriculum” and inserting “or

1 dental or podiatric medicine cur-
 2 riculum”; and

3 (B) in subparagraph (B)—

4 (i) in clause (i)—

5 (I) by inserting “the American
 6 Pharmacists Association, the Accredi-
 7 tation Council on Pharmacy Edu-
 8 cation, the American Psychiatric
 9 Nurses Association, the American
 10 Academy of Nursing, the American
 11 Academy of Family Physicians,” be-
 12 fore “or any other organization”; and

13 (II) by inserting “, the American
 14 Academy of Family Physicians,” be-
 15 fore “or the Accreditation Council”;
 16 and

17 (ii) in clause (ii)—

18 (I) by striking “or accredited
 19 school” and inserting “, an accredited
 20 school”; and

21 (II) by inserting “, or an accred-
 22 ited school of pharmacy” before “in
 23 the United States”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if enacted on December 29, 2022.

SEC. 554. EXTENSION OF TEMPORARY ORDER FOR FENTANYL-RELATED SUBSTANCES.

Effective as if included in the enactment of the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (Public Law 116–114), section 2 of such Act is amended by striking “March 31, 2025” and inserting “September 30, 2026”.

**TITLE VI—PANDEMIC AND ALL-
HAZARDS PREPAREDNESS
AND RESPONSE**

SEC. 601. SHORT TITLE.

This title may be cited as the “Pandemic and All-Hazards Preparedness and Response Act”.

**Subtitle A—State and Local
Readiness and Response**

**SEC. 611. TEMPORARY REASSIGNMENT OF STATE AND
LOCAL PERSONNEL DURING A PUBLIC
HEALTH EMERGENCY.**

Section 319(e) of the Public Health Service Act (42 U.S.C. 247d(e)) is amended—

(1) in paragraph (1), by striking “tribal organization or such Governor or tribal organization’s des-

1 ignee” and inserting “Tribal organization or the des-
2 ignee of the Governor or Tribal organization, or the
3 State or Tribal health official”;

4 (2) in paragraph (2)(B)—

5 (A) in the matter preceding clause (i), by
6 striking “tribal organization” and inserting
7 “Tribal organization, or the State or Tribal
8 health official”; and

9 (B) in clause (v), by striking “tribal orga-
10 nization” and inserting “Tribal organization or
11 State or Tribal health official”;

12 (3) in paragraph (6)—

13 (A) in the matter preceding subparagraph

14 (A)—

15 (i) by striking “Reauthorization Act
16 of 2013” and inserting “and Response
17 Act”; and

18 (ii) by striking “appropriate commit-
19 tees of the Congress” and inserting “Com-
20 mittee on Health, Education, Labor, and
21 Pensions of the Senate and the Committee
22 on Energy and Commerce of the House of
23 Representatives”; and

1 (B) in subparagraph (A), by inserting “,
2 including requests from State or Tribal health
3 officials” before the semicolon;

4 (4) in paragraph (7)(A), by striking “tribal or-
5 ganization” and inserting “Tribal organization”; and

6 (5) in paragraph (8), by striking “March 31,
7 2025” and inserting “December 31, 2026”.

8 **SEC. 612. PUBLIC HEALTH EMERGENCY PREPAREDNESS**
9 **PROGRAM.**

10 Section 319C–1 of the Public Health Service Act (42
11 U.S.C. 247d–3a) is amended—

12 (1) in subsection (b)(2)—

13 (A) in subparagraph (A)(ii), by striking
14 “influenza” and inserting “response planning”;
15 and

16 (B) in subparagraph (H), by inserting “,
17 such as community-based organizations, includ-
18 ing faith-based organizations, and other public
19 and private entities” after “stakeholders”;

20 (2) in subsection (g)—

21 (A) in paragraph (1), in the matter pre-
22 ceding subparagraph (A), by inserting “and the
23 ability of each entity receiving an award under
24 subsection (a) to respond to all-hazards

1 threats” before the period at the end of the
 2 first sentence;

3 (B) in paragraph (2)—

4 (i) in the paragraph heading, by strik-
 5 ing “INFLUENZA” and inserting “RE-
 6 SPONSE”; and

7 (ii) in subparagraph (A)—

8 (I) by striking “to pandemic in-
 9 fluenza” and inserting “to a pathogen
 10 causing a pandemic, including pan-
 11 demic influenza”; and

12 (II) by striking “such pandemic
 13 influenza” and inserting “such pan-
 14 demic response”;

15 (C) in paragraph (5)—

16 (i) in the paragraph heading, by strik-
 17 ing “INFLUENZA” and inserting “PAN-
 18 DEMIC RESPONSE”;

19 (ii) in the matter preceding subpara-
 20 graph (A), by striking “2019” and insert-
 21 ing “2026”;

22 (iii) in subparagraph (A), by striking
 23 “2018” and inserting “2025”; and

1 (iv) in subparagraph (B), by striking
 2 “pandemic influenza” and inserting “a
 3 pathogen causing a pandemic”; and
 4 (D) in paragraph (6)—

5 (i) in subparagraph (A), in the matter
 6 preceding clause (i), by striking “The
 7 amounts described in this paragraph are
 8 the following amounts that are payable to
 9 an entity for activities described in this
 10 section or section 319C–2” and inserting
 11 “The Secretary shall withhold from an en-
 12 tity pursuant to paragraph (5) for non-
 13 compliance with the requirements of this
 14 section or section 319C–2 as follows”; and

15 (ii) in subparagraph (B), by inserting
 16 “with respect to the requirements of this
 17 section or section 319C–2” after “para-
 18 graph (5)”; and

19 (3) in subsection (h)(1)(A), by striking
 20 “\$685,000,000 for each of fiscal years 2019 through
 21 2023” and inserting “\$735,000,000 for each of fis-
 22 cal years 2025 and 2026, to remain available
 23 through December 31, 2026”.

1 **SEC. 613. HOSPITAL PREPAREDNESS PROGRAM.**

2 (a) INCREASING PARTICIPATION BY EMS IN THE
3 HOSPITAL PREPAREDNESS PROGRAM.—

4 (1) IN GENERAL.—Section 319C–2 of the Pub-
5 lic Health Service Act (42 U.S.C. 247d–3b) is
6 amended—

7 (A) in subsection (b)(1)(A)—

8 (i) in clause (iii)(III), by striking “;
9 and” and inserting a semicolon; and

10 (ii) by striking clause (iv) and insert-
11 ing the following:

12 “(iv) one or more emergency medical
13 service organizations; and

14 “(v) to the extent practicable, one or
15 more emergency management organiza-
16 tions; and”; and

17 (B) in subsection (g)(1)—

18 (i) by striking “(1) LOCAL RESPONSE
19 CAPABILITIES” and inserting:

20 “(1) LOCAL RESPONSE CAPABILITIES.—

21 “(A) PROGRAM COORDINATION.—”;

22 (ii) by striking “extent practicable,
23 ensure” and inserting the following: “ex-
24 tent practicable—

25 “(i) ensure”;

1 (iii) by striking the period and insert-
 2 ing “; and”; and

3 (iv) by adding at the end the fol-
 4 lowing:

5 “(ii) seek to increase participation of
 6 eligible entities described in subsection
 7 (b)(1)(A) with lower participation rates
 8 relative to other eligible entities, such as
 9 emergency medical services organizations
 10 and health care facilities in underserved
 11 areas.”.

12 (2) PREFERENCES.—Section 319C–
 13 2(d)(1)(A)(iii) of the Public Health Service Act (42
 14 U.S.C. 247d–3b(d)(1)(A)(iii)) is amended by strik-
 15 ing “subsection (b)(1)(A)(ii)” and inserting “clauses
 16 (ii) and (iv) of subsection (b)(1)(A)”.

17 (b) IMPROVING MEDICAL READINESS AND RESPONSE
 18 CAPABILITIES.—Section 319C–2 of the Public Health
 19 Service Act (42 U.S.C. 247d–3b) is amended—

20 (1) in subsection (b)(2)—

21 (A) in subparagraph (A), by striking
 22 “and” at the end;

23 (B) in subparagraph (B), by striking the
 24 period and inserting “; and”; and

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

1 “(C) designate a lead entity to administer such
2 award and support coordination between entities de-
3 scribed in this subsection.”;

4 (2) in subsection (g)(1), as amended by sub-
5 section (a)(1)(B), by adding at the end the fol-
6 lowing:

7 “(B) REGIONAL OPERATIONS.—An eligible
8 entity shall establish and maintain, or leverage
9 an existing, capability to enable coordination of
10 regional medical operations, which may include
11 systems to facilitate information sharing and
12 coordination, within a coalition described under
13 subsection (b)(1)(A) and, as appropriate,
14 among multiple coalitions that are in close geo-
15 graphic proximity to each other.”; and

16 (3) in subsection (j)(1)—

17 (A) in subparagraph (A), by striking “for
18 each of fiscal years 2019 through 2023” and
19 inserting “for each of fiscal years 2025 and
20 2026, to remain available through December
21 31, 2026”; and

22 (B) in subparagraph (B)(iii), by striking
23 “September 30, 2023” and inserting “Decem-
24 ber 31, 2026”.

1 **SEC. 614. FACILITIES AND CAPACITIES OF THE CENTERS**
 2 **FOR DISEASE CONTROL AND PREVENTION TO**
 3 **COMBAT PUBLIC HEALTH SECURITY**
 4 **THREATS.**

5 Section 319D(h) of the Public Health Service Act (42
 6 U.S.C. 247d–4(h)) is amended—

7 (1) in paragraph (1), by striking “\$25,000,000
 8 for each of fiscal years 2022 and 2023” and insert-
 9 ing “\$40,000,000 for each of fiscal years 2025 and
 10 2026”, to remain available through December 31,
 11 2026; and

12 (2) in paragraph (2), by striking “2022 and
 13 2023” and inserting “2025 and 2026, to remain
 14 available through December 31, 2026”.

15 **SEC. 615. PILOT PROGRAM TO SUPPORT STATE MEDICAL**
 16 **STOCKPILES.**

17 (a) IN GENERAL.—Section 319F–2(i) of the Public
 18 Health Service Act (42 U.S.C. 247d–6b(i)) is amended—

19 (1) in paragraph (2)(B)(i)—

20 (A) in subclause (I), by striking “and
 21 2024” and inserting “through 2025”; and

22 (B) in subclause (II), by striking “2025”
 23 and inserting “2026”;

24 (2) in paragraph (4)—

25 (A) in subparagraph (G), by striking “;
 26 and” at the end and inserting a semicolon;

1 (B) by redesignating subparagraph (H) as
2 subparagraph (I);

3 (C) by inserting after subparagraph (G)
4 the following:

5 “(H) facilitate the sharing of best practices
6 among States within a consortia of States in re-
7 ceipt of funding related to establishing and
8 maintaining a stockpile of medical products;
9 and”; and

10 (D) in subparagraph (I), as so redesign-
11 nated, by striking “State efforts” and inserting
12 “State or regional efforts”;

13 (3) by redesignating paragraphs (5) through
14 (9) as paragraphs (6) through (10), respectively;

15 (4) by inserting after paragraph (4) the fol-
16 lowing:

17 “(5) COORDINATION.—An entity in receipt of
18 an award under paragraph (1), in carrying out the
19 activities under this subsection, shall coordinate with
20 appropriate health care entities, health officials, and
21 emergency management officials within the jurisdic-
22 tion of such State or States.”; and

23 (5) in paragraph (10), as so redesignated, by
24 striking “\$3,500,000,000 for each of fiscal years
25 2023 and 2024” and inserting “\$3,365,000,000 for

1 fiscal year 2025, and \$3,265,000,000 for fiscal year
2 2026”.

3 (b) GAO REPORT.—Section 2409(b) of the PRE-
4 VENT Pandemics Act (Public Law 117–328) is amend-
5 ed—

6 (1) in paragraph (2), by striking “; and” and
7 inserting a semicolon;

8 (2) in paragraph (3), by striking the period and
9 inserting “; and”; and

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

11 “(4) the impact of any regional stockpiling ap-
12 proaches carried out under subsection (i)(1) of sec-
13 tion 319F–2 of the Public Health Service Act (42
14 U.S.C. 247d–6b).”.

15 **SEC. 616. ENHANCING DOMESTIC WASTEWATER SURVEIL-**
16 **LANCE FOR PATHOGEN DETECTION.**

17 (a) IN GENERAL.—Title III of the Public Health
18 Service Act is amended by inserting after section 317V
19 (42 U.S.C. 247b–24) the following:

20 **“SEC. 317W. WASTEWATER SURVEILLANCE FOR PATHOGEN**
21 **DETECTION.**

22 “(a) WASTEWATER SURVEILLANCE SYSTEM.—The
23 Secretary, acting through the Director of the Centers for
24 Disease Control and Prevention and in coordination with
25 other Federal departments and agencies, shall award

1 grants, contracts, or cooperative agreements to eligible en-
 2 tities to establish, maintain, or improve activities related
 3 to the detection and monitoring of infectious diseases
 4 through wastewater for public health emergency prepared-
 5 ness and response purposes.

6 “(b) ELIGIBLE ENTITIES.—To be eligible to receive
 7 an award under this section, an entity shall—

8 “(1) be a State, Tribal, or local health depart-
 9 ment, or a partnership between such a health de-
 10 partment and other public and private entities; and

11 “(2) submit to the Secretary an application at
 12 such time, in such manner, and containing such in-
 13 formation as the Secretary may reasonably require,
 14 which shall include—

15 “(A) a description of activities proposed to
 16 be carried out pursuant to an award under sub-
 17 section (a);

18 “(B) factors such entity proposes to use to
 19 select wastewater sampling sites;

20 “(C) factors such entity proposes to use to
 21 determine whether a response to findings from
 22 such wastewater sampling may be warranted,
 23 and a plan for responding, as appropriate, con-
 24 sistent with applicable plans developed by such
 25 entity pursuant to section 319C–1;

1 “(D) a plan to sustain such wastewater
2 surveillance activities described in such applica-
3 tion following the conclusion of the award pe-
4 riod; and

5 “(E) any additional information the Sec-
6 retary may require.

7 “(c) CONSIDERATION.—In making awards under sub-
8 section (a), the Secretary may give priority to eligible enti-
9 ties that have submitted an application that—

10 “(1) details plans to provide public access to
11 deidentified data generated through such wastewater
12 surveillance activities in a manner that allows for
13 comparison to such data generated by other recipi-
14 ents of an award under subsection (a); and

15 “(2) provides an assessment of community
16 needs related to ongoing infectious disease moni-
17 toring, including estimates of the incidence and
18 prevalence of infectious diseases that can be detected
19 in wastewater and availability, at the time of the ap-
20 plication, of other forms of infectious disease detec-
21 tion in the jurisdiction.

22 “(d) USE OF FUNDS.—An eligible entity shall, as ap-
23 propriate, use amounts awarded under this section to—

1 “(1) establish or enhance existing capacity and
2 capabilities to conduct wastewater sampling, testing,
3 and related analysis;

4 “(2) conduct wastewater surveillance, as appro-
5 priate, in areas or facilities with increased risk of in-
6 fectious disease outbreaks and limited ability to uti-
7 lize other forms of infectious disease detection, such
8 as at individual facilities, institutions, and locations
9 in rural areas or areas in which wastewater is not
10 treated through the relevant local utility of the juris-
11 diction; and

12 “(3) implement projects that use evidence-based
13 or innovative practices to conduct wastewater sur-
14 veillance activities.

15 “(e) PARTNERSHIPS.—In carrying out activities
16 under this section, eligible entities shall identify opportuni-
17 ties to partner with other public or private entities to le-
18 verage relevant capabilities maintained by such entities,
19 as appropriate and consistent with this section.

20 “(f) TECHNICAL ASSISTANCE.—The Secretary, in
21 consultation with the heads of other applicable Federal
22 agencies and departments, as appropriate, shall provide
23 technical assistance to recipients of awards under this sec-
24 tion to facilitate the planning, development, and imple-
25 mentation of activities described in subsection (d).

1 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
2 carry out this section, there is authorized to be appro-
3 priated \$20,000,000 for each of fiscal years 2025 and
4 2026, to remain available through December 31, 2026.”.

5 (b) WASTEWATER SURVEILLANCE RESEARCH.—

6 (1) IN GENERAL.—The Secretary of Health and
7 Human Services (in this subsection referred to as
8 the “Secretary”) shall continue to conduct or sup-
9 port research on the use of wastewater surveillance
10 to detect and monitor emerging infectious diseases,
11 which may include—

12 (A) research to improve the efficiency and
13 effectiveness of wastewater sample collection
14 and analysis and increase the sensitivity and
15 specificity of wastewater testing methods; and

16 (B) implementation and development of
17 evidence-based practices to facilitate the esti-
18 mation of the incidence and prevalence of infec-
19 tious disease within a community.

20 (2) NON-DUPLICATION OF EFFORT.—The Sec-
21 retary shall ensure that activities carried out under
22 this subsection do not unnecessarily duplicate efforts
23 of other agencies and offices within the Department
24 of Health and Human Services related to wastewater
25 surveillance.

1 **SEC. 617. REAUTHORIZATION OF MOSQUITO ABATEMENT**
2 **FOR SAFETY AND HEALTH PROGRAM.**

3 Section 317S of the Public Health Service Act (42
4 U.S.C. 247b–21) is amended—

5 (1) in subsection (a)(3)(A), by striking “sub-
6 section (b)(3)” and inserting “subsection (b)(4)”;

7 (2) in subsection (b)—

8 (A) by redesignating paragraphs (3)
9 through (6) as paragraphs (4) through (7), re-
10 spectively; and

11 (B) by inserting after paragraph (2) the
12 following:

13 “(3) CONSIDERATIONS.—The Secretary may
14 consider the use of innovative and novel technology
15 for mosquito prevention and control in making
16 grants under paragraph (1).”;

17 (3) by amending subsection (d) to read as fol-
18 lows:

19 “(d) USES OF FUNDS.—Amounts appropriated under
20 subsection (f) may be used by the Secretary to provide
21 training and technical assistance with respect to the plan-
22 ning, development, and operation of assessments and
23 plans under subsection (a) and control programs under
24 subsection (b). The Secretary may provide such training
25 and technical assistance directly or through awards of
26 grants or contracts to public and private entities.”; and

1 (4) in subsection (f)(1), by striking “2019
 2 through 2023” and inserting “2025 and 2026, to re-
 3 main available through December 31, 2026”.

4 **Subtitle B—Federal Planning and** 5 **Coordination**

6 **SEC. 621. ALL-HAZARDS EMERGENCY PREPAREDNESS AND** 7 **RESPONSE.**

8 Section 2811 of the Public Health Service Act (42
 9 U.S.C. 300hh–10) is amended—

10 (1) in subsection (b)—

11 (A) in paragraph (3)—

12 (i) by striking “Oversee advanced re-
 13 search, development, and procurement”
 14 and inserting the following:

15 “(A) IN GENERAL.—Oversee advanced re-
 16 search, development, procurement, and replen-
 17 ishment”; and

18 (ii) by adding at the end the fol-
 19 lowing:

20 “(B) DEVELOPMENT OF REQUIRE-
 21 MENTS.—Lead the development and approval,
 22 and, on a routine basis, the review and update,
 23 of requirements for such countermeasures and
 24 products, including related capabilities, to in-
 25 form the advanced research, development, pro-

1 curement, and replenishment decisions of the
2 Secretary.”;

3 (B) in paragraph (4)—

4 (i) in subparagraph (F)—

5 (I) in the matter preceding clause
6 (i), by striking “and in consultation
7 with the Secretary of Homeland Secu-
8 rity,”; and

9 (II) in clause (i), by inserting
10 “enhance” after “capabilities and”;

11 (ii) in subparagraph (G)—

12 (I) in the matter preceding clause
13 (i), by inserting “the Office of Pan-
14 demic Preparedness and Response
15 Policy,” after “Veterans Affairs,”;

16 (II) in clause (i), by striking
17 “based on” and inserting “based on—
18 ”;

19 (III) in clause (ii), by striking “;
20 and” at the end and inserting a semi-
21 colon;

22 (IV) in clause (iii), by striking
23 the period and inserting “; and”; and

24 (V) by adding at the end the fol-
25 lowing:

“(iv) that include, as appropriate, participation by relevant industry, academia, professional societies, and other stakeholders.”;

(iii) in subparagraph (H)—

(I) by inserting “and the Director of the Office of Pandemic Preparedness and Response Policy” after “Security Affairs”; and

(II) by inserting “and medical product and supply capacity planning pursuant to subparagraph (J), including discussion of any relevant identified supply chain vulnerabilities” before the period at the end;

(iv) in subparagraph (I), by inserting “the Director of the Office of Pandemic Preparedness and Response Policy,” after “Security Affairs,”; and

(v) in subparagraph (J)(i), in the matter preceding subclause (I), by inserting “(including ancillary medical supplies and components of medical products, such as active pharmaceutical ingredients, key starting materials, medical device compo-

nents, testing kits, reagents, and other testing supplies)” after “supply needs”; and

(C) in paragraph (7)—

(i) in the matter preceding subparagraph (A), by inserting “and the requirements developed pursuant to paragraph (3)(B)” after “subsection (d)”;

(ii) by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively; and

(iii) by inserting after subparagraph (D) the following:

“(E) include a professional judgment of anticipated budget needs for each future fiscal year accounted for in such plan to account for the full range of anticipated medical countermeasure needs and life-cycle costs to address such priorities and requirements;”;

(2) in subsection (d)—

(A) by amending paragraph (1) to read as follows:

“(1) IN GENERAL.—Not later than March 15, 2020, and biennially thereafter, the Assistant Secretary for Preparedness and Response shall develop

1 and submit to the Committee on Health, Education,
 2 Labor, and Pensions of the Senate and the Com-
 3 mittee on Energy and Commerce of the House of
 4 Representatives a coordinated strategy for medical
 5 countermeasures to address chemical, biological, ra-
 6 diological, and nuclear threats, informed by the re-
 7 quirements developed pursuant to subsection
 8 (b)(3)(B). Not later than 180 days after the submis-
 9 sion of such strategy to such committees, the Assist-
 10 ant Secretary for Preparedness and Response shall
 11 submit an accompanying implementation plan to
 12 such committees. In developing such a strategy and
 13 plan, the Assistant Secretary for Preparedness and
 14 Response shall consult with the Public Health Emer-
 15 gency Medical Countermeasures Enterprise estab-
 16 lished under section 2811–1. Such strategy and plan
 17 shall be known as the Public Health Emergency
 18 Medical Countermeasures Enterprise Strategy and
 19 Implementation Plan.”; and

20 (B) in paragraph (2), in the matter pre-
 21 ceding subparagraph (A), by inserting “strategy
 22 and” before “plan”; and

23 (3) in subsection (f)—

24 (A) in paragraph (1), in the matter pre-
 25 ceding subparagraph (A), by inserting “, includ-

ing such agents that are an emerging infectious disease” after “become a pandemic”; and

(B) in paragraph (2)(A), by striking “\$250,000,000 for each of fiscal years 2019 through 2023” and inserting “\$335,000,000 for each of fiscal years 2025 and 2026, to remain available through December 31, 2026”.

SEC. 622. NATIONAL HEALTH SECURITY STRATEGY.

Section 2802 of the Public Health Service Act (42 U.S.C. 300hh–1) is amended—

(1) in subsection (a)(3)—

(A) by striking “In 2022, the” and inserting “The”; and

(B) by inserting “, maintaining, and sustaining” after “establishing”; and

(2) in subsection (b)—

(A) in paragraph (2)—

(i) in subparagraph (A), by inserting “that support interagency coordination and availability of information, as appropriate” before the period;

(ii) in subparagraph (B), by inserting “rapid testing,” after “and supplies,”;

(B) in paragraph (3)—

1 (i) in the matter preceding subpara-
2 graph (A), by inserting “and blood banks”
3 after “dental health facilities”;

4 (ii) in subparagraph (C), by inserting
5 “and current capacity of facilities within
6 such systems, as applicable” before the pe-
7 riod; and

8 (iii) in subparagraph (D), by inserting
9 “and other medical products and medical
10 supplies consistent with the activities car-
11 ried out under section 2811(b)(4)(J)” be-
12 fore the period;

13 (C) in paragraph (5), by inserting “appli-
14 cable federally funded activities and” after “(in-
15 cluding”;

16 (D) in paragraph (8)—

17 (i) in subparagraph (A), by inserting
18 “public health and medical” before “activi-
19 ties”; and

20 (ii) in subparagraph (B), by striking
21 “familiarity with” and inserting “under-
22 standing of, and coordination between,”;

23 (E) by redesignating paragraphs (9) and
24 (10) as paragraphs (10) and (12), respectively;

1 (F) by inserting after paragraph (8) the
2 following:

3 “(9) OTHER SETTINGS.—Supporting Federal,
4 State, local, and Tribal coordination and planning
5 with respect to facilities in which there is an in-
6 creased risk of infectious disease outbreaks, includ-
7 ing such facilities that address the needs of at-risk
8 individuals, in the event of a public health emer-
9 gency declared under section 319.”;

10 (G) by inserting after subparagraph (10),
11 as so redesignated, the following:

12 “(11) OTHER HAZARDS.—Assessing current
13 and potential health security threats from natural
14 disasters with respect to public health and medical
15 preparedness and response.”;

16 (H) by inserting after paragraph (12), as
17 so redesignated, the following:

18 “(13) CYBERSECURITY RESILIENCY OF HEALTH
19 CARE SYSTEMS.—Consistent with the requirements
20 of section 2218 of the Homeland Security Act of
21 2002, strengthening the ability of States, local com-
22 munities, and Tribal communities to prepare for, re-
23 spond to, and be resilient against cybersecurity
24 vulnerabilities or cybersecurity attacks that affect
25 public health and health information technology, and

1 encouraging health care facilities to use recognized
2 security practices meeting or exceeding the ap-
3 proaches established under section 405(d) of the Cy-
4 bersecurity Act of 2015.”; and

5 (I) by striking “tribal” each place it ap-
6 pears and inserting “Tribal”.

7 **SEC. 623. IMPROVING DEVELOPMENT AND DISTRIBUTION**
8 **OF DIAGNOSTIC TESTS.**

9 Section 319B of the Public Health Service Act (42
10 U.S.C. 247d–2) is amended to read as follows:

11 **“SEC. 319B. IMPROVING DEVELOPMENT AND DISTRIBUTION**
12 **OF DIAGNOSTIC TESTS.**

13 “(a) **DIAGNOSTIC TESTING PREPAREDNESS PLAN.**—
14 The Secretary shall develop, make publicly available, not
15 later than 1 year after the date of enactment of the Pan-
16 demic and All-Hazards Preparedness and Response Act,
17 and update not less frequently than every 3 years there-
18 after, a plan for the rapid development, validation, author-
19 ization, manufacture, procurement, and distribution of di-
20 agnostic tests, and for rapid scaling of testing capacity,
21 in response to chemical, biological, radiological, or nuclear
22 threats, including emerging infectious diseases, for which
23 a public health emergency is declared under section 319,
24 or that has significant potential to cause such a public
25 health emergency.

1 “(b) PURPOSES.—The purpose of the plan under sub-
2 section (a) shall be to—

3 “(1) facilitate the development and utilization
4 of diagnostic tests;

5 “(2) describe the processes for the rapid devel-
6 opment, validation, authorization, manufacture, pro-
7 curement, and distribution of diagnostic tests, and
8 for rapid scaling of testing capacity; and

9 “(3) facilitate coordination and collaboration
10 among public and private entities to improve the
11 rapid development and utilization of diagnostic test-
12 ing during a public health emergency.

13 “(c) CONSIDERATIONS.—The plan under subsection
14 (a) shall take into consideration—

15 “(1) domestic capacity, including any such ca-
16 pacity established through partnerships with public
17 and private entities pursuant to subsection (e), to
18 support the development, validation, manufacture,
19 procurement, and distribution of tests, and the rapid
20 scaling of testing capacity;

21 “(2) novel technologies and platforms that—

22 “(A) may be used to improve testing capa-
23 bilities, including—

24 “(i) high-throughput laboratory
25 diagnostics;

1 “(ii) point-of-care diagnostics; and

2 “(iii) rapid at-home diagnostics;

3 “(B) improve the accessibility of diagnostic
4 tests; and

5 “(C) facilitate the development and manu-
6 facture of diagnostic tests;

7 “(3) medical supply needs related to testing, in-
8 cluding diagnostic testing, equipment, supplies, and
9 component parts, and any potential vulnerabilities
10 related to the availability of such medical supplies
11 and related planning needs, consistent with section
12 2811(b)(4)(J);

13 “(4) strategies for the rapid and efficient dis-
14 tribution of tests locally, regionally, or nationwide
15 and appropriate scaling of laboratory testing capac-
16 ity; and

17 “(5) assessment of such strategies through
18 drills and operational exercises carried out under
19 section 2811(b)(4)(G), as appropriate.

20 “(d) COORDINATION.—To inform the development
21 and update of the plan under subsection (a), and in car-
22 rying out activities to implement such plan, the Secretary
23 shall coordinate with industry, such as device manufactur-
24 ers, clinical and reference laboratories, and medical prod-
25 uct distributors, States, local governmental entities, In-

1 dian Tribes and Tribal organizations, and other relevant
2 public and private entities.

3 “(e) CAPACITY BUILDING.—The Secretary may con-
4 tract with public and private entities, as appropriate, to
5 increase domestic capacity in the rapid development, vali-
6 dation, authorization, manufacture, procurement, and dis-
7 tribution of diagnostic tests, as appropriate, to State,
8 local, and Tribal health departments and other appro-
9 priate entities for immediate public health response activi-
10 ties to address an infectious disease with respect to which
11 a public health emergency is declared under section 319,
12 or that has significant potential to cause such a public
13 health emergency.”.

14 **SEC. 624. COMBATING ANTIMICROBIAL RESISTANCE.**

15 (a) IN GENERAL.—Section 319E of the Public
16 Health Service Act (42 U.S.C. 247d–5) is amended—

17 (1) in subsection (a)—

18 (A) in paragraph (1), by inserting “and ac-
19 tivities” after “Federal programs”;

20 (B) in paragraph (2)—

21 (i) by striking “public health constitu-
22 encies, manufacturers, veterinary and med-
23 ical professional societies and others” and
24 inserting “the Advisory Council described

1 in subsection (b) and relevant public and
2 private entities”; and

3 (ii) by inserting “, pursuant to para-
4 graph (4),” after “comprehensive plan”;

5 (C) by amending paragraph (3) to read as
6 follows:

7 “(3) AGENDA.—The task force described in
8 paragraph (1) shall consider factors the Secretary
9 considers appropriate, including factors to—

10 “(A) slow the emergence of resistant bac-
11 teria and fungi and prevent the spread of re-
12 sistant infections;

13 “(B) strengthen activities to combat resist-
14 ance with respect to zoonotic diseases;

15 “(C) advance development and use of rapid
16 and innovative capabilities, including diagnostic
17 tests, for identification and characterization of
18 resistant bacteria and fungi;

19 “(D) accelerate basic and applied research
20 and development for new antibiotics,
21 antifungals, and other related therapeutics and
22 vaccines; and

23 “(E) support international collaboration
24 and capacities for antimicrobial-resistance pre-
25 vention, detection, and control.”;

1 (D) by redesignating paragraph (4) as
2 paragraph (5);

3 (E) by inserting after paragraph (3) the
4 following:

5 “(4) ACTION PLAN.—Not later than October 1,
6 2026, and every 5 years thereafter, the task force
7 described in paragraph (1) shall develop and submit
8 to the Committee on Health, Education, Labor, and
9 Pensions and the Committee on Appropriations of
10 the Senate and the Committee on Energy and Com-
11 merce and the Committee on Appropriations of the
12 House of Representatives a plan regarding Federal
13 programs and activities to combat antimicrobial re-
14 sistance, including measurable outcomes, as appro-
15 priate, informed by—

16 “(A) the agenda described in paragraph
17 (3);

18 “(B) input provided by the Advisory Coun-
19 cil described in subsection (b); and

20 “(C) input from other relevant stake-
21 holders provided pursuant to paragraph (2).”;

22 (2) by redesignating subsections (b) through (o)
23 as subsections (c) through (p), respectively;

24 (3) by inserting after subsection (a) the fol-
25 lowing:

1 “(b) ADVISORY COUNCIL.—

2 “(1) IN GENERAL.—The Secretary may con-
3 tinue the Presidential Advisory Council on Com-
4 bating Antibiotic-Resistant Bacteria, referred to in
5 this subsection as the ‘Advisory Council’.

6 “(2) DUTIES.—The Advisory Council shall ad-
7 vise and provide information and recommendations
8 to the Secretary, acting through the Task Force es-
9 tablished under subsection (a), regarding Federal
10 programs and activities intended to reduce or com-
11 bat antimicrobial-resistant bacteria or fungi that
12 may present a public health threat and improve ca-
13 pabilities to prevent, diagnose, mitigate, or treat
14 such resistance. Such advice, information, and rec-
15 ommendations may be related to improving Federal
16 efforts related to factors described in subsection
17 (a)(3) and other topics related to antimicrobial re-
18 sistance, as appropriate.

19 “(3) MEETINGS AND COORDINATION.—

20 “(A) MEETINGS.—The Advisory Council
21 shall meet not less frequently than biannually
22 and, to the extent practicable, in coordination
23 with meetings of the task force established
24 under subsection (a).

1 “(B) COORDINATION.—The Advisory
2 Council shall, to the greatest extent practicable,
3 coordinate activities carried out by the Council
4 with the task force established under subsection
5 (a).

6 “(4) FACA.—Chapter 10 of title 5, United
7 States Code, shall apply to the activities and duties
8 of the Advisory Council.

9 “(5) SUNSET.—

10 “(A) IN GENERAL.—The Advisory Council
11 under this subsection shall terminate on De-
12 cember 31, 2026.

13 “(B) EXTENSION OF ADVISORY COUN-
14 CIL.—Not later than October 1, 2026, the Sec-
15 retary shall submit to the Committee on
16 Health, Education, Labor, and Pensions of the
17 Senate and the Committee on Energy and Com-
18 merce of the House of Representatives a report
19 that includes a recommendation on whether the
20 Advisory Council should be extended, and iden-
21 tifying whether there are other committees,
22 councils, or task forces that have overlapping or
23 similar duties to that of the Advisory Council,
24 and whether such committees, councils, or task
25 forces should be combined, restructured, or

1 eliminated, including with respect to the task
2 force established under subsection (a).”; and

3 (4) in subsection (n), as so redesignated, by
4 striking “(f) through (j)” and inserting “(g) through
5 (k)”.

6 (b) CONFORMING AMENDMENT.—Section 505 of the
7 Pandemic and All-Hazards Preparedness and Advancing
8 Innovation Act of 2019 (42 U.S.C. 247d–5 note; Public
9 Law 116–22) is amended by striking subsection (a) and
10 all that follows through “Not later” in subsection (e) and
11 inserting the following:

12 “Not later”.

13 **SEC. 625. STRATEGIC NATIONAL STOCKPILE AND MATE-**
14 **RIAL THREATS.**

15 Section 319F–2 of the Public Health Service Act (42
16 U.S.C. 247d–6b) is amended—

17 (1) in subsection (a)—

18 (A) in paragraph (2)—

19 (i) in subparagraph (A), by inserting
20 “Such review shall include a description of
21 how the Secretary manages and mitigates
22 risks associated with gaps between current
23 inventory levels and stockpiling goals,
24 prioritizes such risks, and tracks progress

1 toward mitigation of such risks.” after the
2 first sentence; and

3 (ii) in subparagraph (B)(i), by amend-
4 ing subclause (IV) to read as follows:

5 “(IV) the emergency health secu-
6 rity threat or threats such counter-
7 measure procurement is intended to
8 address, including—

9 “(aa) whether such procure-
10 ment is consistent with meeting
11 emergency health security needs
12 associated with such threat or
13 threats; and

14 “(bb) in the case of a coun-
15 termeasure that addresses a bio-
16 logical agent, whether such agent
17 has an increased likelihood to be-
18 come resistant to, more resistant
19 to, or evade, such counter-
20 measure relative to other avail-
21 able medical countermeasures;”;

22 (B) in paragraph (3)—

23 (i) in subparagraph (B), by striking
24 “are followed, regularly reviewed, and up-
25 dated with respect to such stockpile” and

1 inserting “with respect to such stockpile
2 are followed, regularly reviewed, and up-
3 dated to reflect best practices”;

4 (ii) in subparagraph (I), by inserting
5 “, through a standard operating proce-
6 dure,” after “ensure”;

7 (iii) by redesignating subparagraphs
8 (H) through (K) as subparagraphs (I)
9 through (L), respectively;

10 (iv) by inserting after subparagraph
11 (G) the following:

12 “(H) utilize tools to enable the timely and
13 accurate tracking of the contents of the stock-
14 pile throughout the deployment of such con-
15 tents, including tracking of the location and ge-
16 ographic distribution and utilization of such
17 contents;”;

18 (v) in subparagraph (K), as so redes-
19 ignated, by striking “; and” at the end and
20 inserting a semicolon;

21 (vi) in subparagraph (L), as so redes-
22 ignated, by striking the period and insert-
23 ing “; and”; and

24 (vii) by adding at the end the fol-
25 lowing:

1 “(M) communicate to relevant vendors re-
2 garding modifications, renewals, extensions, or
3 terminations of contracts, or the intent to exer-
4 cise options for such contracts, within 30 days,
5 as practicable, of such determination, including
6 through the development of a contract notifica-
7 tion process.”;

8 (C) in paragraph (5)(B), in the matter
9 preceding clause (i), by inserting “, which may
10 accompany the review required under paragraph
11 (2),” after “Representatives a report”; and

12 (D) in paragraph (6)(A)—

13 (i) by redesignating clauses (viii)
14 through (x) as clauses (ix) through (xi), re-
15 spectively; and

16 (ii) by inserting after clause (vii) the
17 following:

18 “(viii) with respect to any change in
19 the Federal organizational management of
20 the stockpile, an assessment and compari-
21 son of any differences in the processes and
22 operations resulting from such change, in-
23 cluding—

1 “(I) planning for potential coun-
 2 termeasure deployment, distribution,
 3 or dispensing capabilities;

4 “(II) organizational structure;

5 “(III) communication with rel-
 6 evant stakeholders related to procure-
 7 ment decisions;

8 “(IV) processes related to pro-
 9 curement, deployment, and use of
 10 stockpiled countermeasures;

11 “(V) communication and coordi-
 12 nation with the Public Health Emer-
 13 gency Medical Countermeasures En-
 14 terprise and other related Federal en-
 15 tities;

16 “(VI) inventory management;
 17 and

18 “(VII) availability and use of re-
 19 sources for such activities;” and

20 (2) in subsection (c)(2)(C), by striking
 21 “promptly” and inserting “, not later than 60 days
 22 after each such determination,”;

23 (3) in subsection (f)(1), by striking
 24 “\$610,000,000 for each of fiscal years 2019 through
 25 2021, and \$750,000,000 for each of fiscal years

1 2022 and 2023” and inserting “\$1,100,000,000 for
 2 fiscal year 2025, and \$1,210,000,000 for fiscal year
 3 2026”; and

4 (4) in subsection (g)(1), by striking “2019
 5 through 2028” and inserting “2025 through 2034”.

6 **SEC. 626. MEDICAL COUNTERMEASURES FOR VIRAL**
 7 **THREATS WITH PANDEMIC POTENTIAL.**

8 Section 319L of the Public Health Service Act (42
 9 U.S.C. 247d–7e) is amended—

10 (1) in subsection (c)—

11 (A) in paragraph (4)—

12 (i) in subparagraph (D)—

13 (I) in clause (ii), by striking “;
 14 and” and inserting a semicolon; and

15 (II) by redesignating clause (iii)
 16 as clause (iv); and

17 (III) by inserting after clause (ii)
 18 the following:

19 “(iii) research and development of
 20 medical countermeasures for priority virus
 21 families that have significant potential to
 22 cause a pandemic, including such counter-
 23 measures that take either pathogen-specific
 24 or pathogen-agnostic approaches, and plat-
 25 form technologies to improve the develop-

1 ment and manufacture of such medical
2 countermeasures; and”; and

3 (ii) in subparagraph (F)(ii), by insert-
4 ing “or priority virus families and other
5 viral pathogens that pose a threat due to
6 their significant potential to cause a pan-
7 demic,” after “pandemic influenza,”; and

8 (B) in paragraph (5), by adding at the end
9 the following:

10 “(I) NOTIFICATION.—In awarding con-
11 tracts, grants, cooperative agreements, or other
12 transactions under this section, the Secretary
13 shall communicate to relevant vendors regard-
14 ing modifications, renewals, extensions, or ter-
15 minations of contracts, including through the
16 development of a contract notification process,
17 within 30 days of such determination, as prac-
18 ticable.”;

19 (2) in subsection (d)(2), by striking
20 “\$611,700,000 for each of fiscal years 2019 through
21 2023” and inserting “\$950,000,000 for each of fis-
22 cal years 2025 and 2026”; and

23 (3) in subsection (e)(1), by amending subpara-
24 graph (D) to read as follows:

1 “(D) SUNSET.—This paragraph shall cease
2 to have force or effect after December 31,
3 2026.”.

4 **SEC. 627. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
5 **TERMEASURES ENTERPRISE.**

6 Section 2811–1 of the Public Health Service Act (42
7 U.S.C. 300hh–10a) is amended—

8 (1) in subsection (b)—

9 (A) by redesignating paragraph (11) as
10 paragraph (13);

11 (B) by inserting after paragraph (10) the
12 following:

13 “(11) The Director of the Biomedical Advanced
14 Research and Development Authority.

15 “(12) The Director of the Strategic National
16 Stockpile.”; and

17 (C) in paragraph (13), as so redesignated,
18 by striking “the Director of the Biomedical Ad-
19 vanced Research and Development Authority,
20 the Director of the Strategic National Stock-
21 pile, the Director of the National Institute of
22 Allergy and Infectious Diseases,” and inserting
23 “the Director of the National Institute of Al-
24 lergy and Infectious Diseases”; and

25 (2) in subsection (c)—

1 (A) in paragraph (1)—

2 (i) by redesignating subparagraph (D)

3 as subparagraph (E); and

4 (ii) by inserting after subparagraph

5 (C) the following:

6 “(D) Assist the Secretary in developing
7 strategies for appropriate and evidence-based
8 allocation and distribution of countermeasures
9 to jurisdictions, in a manner that supports the
10 availability and use of such countermeasures,
11 for public health and medical preparedness and
12 response needs.”;

13 (B) in paragraph (2), by inserting “rel-
14 evant stakeholders, including industry,” after
15 “consider input from”; and

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

17 “(3) INFORMATION SHARING.—The Secretary
18 shall, as appropriate and in a manner that does not
19 compromise national security, communicate and
20 share information related to recommendations made
21 and strategies developed under paragraph (1) with
22 relevant stakeholders, including industry and State,
23 local, and Tribal public health departments.”.

1 **SEC. 628. FELLOWSHIP AND TRAINING PROGRAMS.**

2 Section 317G of the Public Health Service Act (42
3 U.S.C. 247b–8) is amended—

4 (1) by striking “The Secretary,” and inserting
5 the following:

6 “(a) IN GENERAL.—The Secretary,”; and

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

8 “(b) NONCOMPETITIVE CONVERSION.—

9 “(1) IN GENERAL.—The Secretary may non-
10 competitively convert an individual who has com-
11 pleted an epidemiology, surveillance, or laboratory
12 fellowship or training program under subsection (a)
13 to a career-conditional appointment without regard
14 to the provisions of subchapter I of chapter 33 of
15 title 5, United States Code, provided that such indi-
16 vidual meets qualification requirements for the ap-
17 pointment.”.

18 **SEC. 629. REGIONAL BIOCONTAINMENT RESEARCH LAB-**
19 **ORATORIES.**

20 (a) IN GENERAL.—The Secretary of Health and
21 Human Services (referred to in this section as the “Sec-
22 retary”) shall make awards to establish or maintain, as
23 applicable, not fewer than 12 regional biocontainment lab-
24 oratories, for purposes of—

25 (1) conducting biomedical research to support
26 public health and medical preparedness for, and

1 rapid response to, biological agents, including emerg-
2 ing infectious diseases;

3 (2) ensuring the availability of surge capacity
4 for purposes of responding to such biological agents;

5 (3) supporting information sharing between,
6 and the dissemination of findings to, researchers and
7 other relevant individuals to facilitate collaboration
8 between industry and academia; and

9 (4) providing, as appropriate and applicable,
10 technical assistance and training to researchers and
11 other relevant individuals to support the biomedical
12 research workforce in improving the management
13 and mitigation of safety and security risks in the
14 conduct of research involving such biological agents.

15 (b) REQUIREMENTS.—As a condition of receiving a
16 grant under this section, a regional biocontainment labora-
17 tory shall agree to such oversight activities as the Sec-
18 retary determines appropriate, including periodic meetings
19 with relevant officials of the Department of Health and
20 Human Services, facility inspections, and other activities
21 as necessary and appropriate to ensure compliance with
22 the terms and conditions of such award.

23 (c) WORKING GROUP.—The Secretary shall establish
24 a Working Group, consisting of a representative from each
25 entity in receipt of an award under subsection (a). The

1 Working Group shall make recommendations to the Sec-
2 retary in administering awards under this section, for pur-
3 poses of—

4 (1) improving the quality and consistency of ap-
5 plicable procedures and practices within laboratories
6 funded pursuant to subsection (a); and

7 (2) ensuring coordination, as appropriate, of
8 federally funded activities carried out at such labora-
9 tories.

10 (d) DEFINITION.—In this section, the term “regional
11 biocontainment laboratory” means a Biosafety or Animal
12 Biosafety Level–3 and Level–2 facility located at an insti-
13 tution in the United States that is designated by the Sec-
14 retary to carry out the activities described in subsection
15 (a).

16 (e) AUTHORIZATION OF APPROPRIATIONS.—To carry
17 out this section, there are authorized to be appropriated
18 \$52,000,000 for each of fiscal years 2025 and 2026, to
19 remain available through December 31, 2026.

20 (f) ADMINISTRATIVE EXPENSES.—Of the amount
21 available to carry out this section for a fiscal year, the
22 Secretary may use not more than 5 percent for the admin-
23 istrative expenses of carrying out this section, including
24 expenses related to carrying out subsection (c).

1 (g) REPORT TO CONGRESS.—Not later than 1 year
2 after the date of the enactment of this Act, and biannually
3 thereafter, the Secretary, in consultation with the heads
4 of applicable Federal departments and agencies shall re-
5 port to the Committee on Health, Education, Labor, and
6 Pensions of the Senate and the Committee on Energy and
7 Commerce of the House of Representatives on—

8 (1) the activities and accomplishments of the
9 regional biocontainment laboratories;

10 (2) any published or disseminated research
11 findings based on research conducted in such labora-
12 tories in the applicable year;

13 (3) oversight activities carried out by the Sec-
14 retary pursuant to subsection (b);

15 (4) activities undertaken by the Secretary to
16 take into consideration the capacity and capabilities
17 of the network of regional biocontainment labora-
18 tories in activities to prepare for and respond to bio-
19 logical agents, which may include leveraging such ca-
20 pacity and capabilities to support the Laboratory
21 Response Network, as applicable and appropriate;

22 (5) plans for the maintenance and sustainment
23 of federally funded activities conducted at the re-
24 gional biocontainment laboratories, consistent with
25 the strategy required under section 2312 of the

1 PREVENT Pandemics Act (Public Law 117–328);
2 and

3 (6) activities undertaken by the Secretary to co-
4 ordinate with the heads of other relevant Federal de-
5 partments and agencies to ensure that work carried
6 out by each such facility on behalf of the Secretary
7 and such other relevant heads is prioritized, is com-
8 plementary to the work carried out by other such fa-
9 cilities and other relevant federally funded activities,
10 and avoids unnecessary duplication.

11 **SEC. 629A. LIMITATION RELATED TO COUNTRIES OF CON-**
12 **CERN CONDUCTING CERTAIN RESEARCH.**

13 Section 2315(c) of the PREVENT Pandemics Act
14 (42 U.S.C. 6627) is amended to read as follows:

15 “(c) LIMITATIONS ON COUNTRIES OF CONCERN CON-
16 DUCTING CERTAIN RESEARCH.—

17 “(1) IN GENERAL.—The Secretary of Health
18 and Human Services (referred to in this subsection
19 as the ‘Secretary’) shall not fund research that may
20 reasonably be anticipated to involve the creation,
21 transfer, and use of enhanced pathogens of pan-
22 demic potential or biological agents or toxins listed
23 pursuant to section 351A(a)(1) of the Public Health
24 Service Act if such research is conducted by a for-
25 eign entity at a facility located in a country that is

determined to be a country of concern as defined in paragraph (2).

“(2) COUNTRIES OF CONCERN.—

“(A) DEFINITION.—For purposes of this subsection, a ‘country of concern’ means the People’s Republic of China, the Democratic People’s Republic of Korea, the Russian Federation, the Islamic Republic of Iran, and any other country as determined pursuant to subparagraph (B).

“(B) ADDITIONAL COUNTRIES.—The Director of National Intelligence (referred to in this subsection as the ‘Director’) shall, in consultation with the Secretary, add additional countries of concern for purposes of paragraph (1), only if—

“(i) the Director determines that evidence exists that a country has malicious intent related to the creation, enhancement, transfer, or use of pathogens of pandemic potential or biological agents or toxins listed pursuant to such section 351A(a)(1); and

“(ii) in a manner that does not compromise national security, the Director

1 provides such evidence in a report sub-
2 mitted to the Committee on Health, Edu-
3 cation, Labor, and Pensions of the Senate
4 and the Committee on Energy and Com-
5 merce of the House of Representatives.

6 “(C) LIMITATION.—Paragraph (1) shall
7 not take effect with respect to a country of con-
8 cern identified under subparagraph (B) until
9 the date that is 15 days after the date on which
10 the Director submits the report described in
11 subparagraph (B)(ii).

12 “(3) CLARIFICATION.—

13 “(A) IN GENERAL.—The requirement of
14 paragraph (1) may be waived by the President
15 for the duration of the initial response to an
16 outbreak of a novel emerging infectious disease
17 if the President determines that such require-
18 ment impedes the ability of the Federal Govern-
19 ment to immediately respond to such outbreak.

20 “(B) NOTIFICATION.—The President shall
21 notify such committees of Congress not later
22 than 48 hours after exercising the waiver under
23 subparagraph (A), and shall provide updates to
24 such committees related to the use of such
25 waiver every 15 days thereafter.

1 “(4) SUNSET.—The limitation under this sub-
 2 section shall expire on December 31, 2026.”.

3 **Subtitle C—Addressing the Needs**
 4 **of All Individuals**

5 **SEC. 631. IMPROVING ACCESS TO CERTAIN PROGRAMS.**

6 (a) PROCEDURES RELATED TO THE TRANSITION OF
 7 CERTAIN CLAIMS.—

8 (1) PROCEDURES FOR CORRECTING SUBMIS-
 9 SIONS.—

10 (A) REQUESTS INITIALLY SUBMITTED
 11 UNDER SECTION 319F–4.—

12 (i) IN GENERAL.—In the case of a re-
 13 quest for compensation submitted under
 14 section 319F–4 of the Public Health Serv-
 15 ice Act (42 U.S.C. 247d–6e) for an injury
 16 or death related to a medical product for
 17 active immunization to prevent coronavirus
 18 disease 2019 that the Secretary determines
 19 to be ineligible pursuant to subsection
 20 (b)(4)(B) of such section 319F–4, the Sec-
 21 retary shall, not later than 30 days after
 22 such determination, notify the individual
 23 submitting the request of such determina-
 24 tion.

1 (ii) SUBMISSION OF PETITION.—An
2 individual who receives a notification de-
3 scribed in clause (i) shall be eligible to sub-
4 mit a petition to the United States Court
5 of Federal Claims under section 2111 of
6 the Public Health Service Act (42 U.S.C.
7 300aa–11) with respect to the same med-
8 ical product administration claimed in the
9 request submitted under section 319F–4 of
10 such Act (42 U.S.C. 247d–6e), provided
11 such petition is submitted not later than
12 the later of—

13 (I) 1 year after receiving such
14 notification under clause (i); or

15 (II) the last date on which the
16 individual otherwise would be eligible
17 to submit a petition relating to such
18 injury, as specified in section 2116 of
19 such Act (42 U.S.C. 300aa–16).

20 (iii) ELIGIBILITY.—To be eligible to
21 submit a petition in accordance with clause
22 (ii), the petitioner shall have submitted the
23 request that was determined to be ineli-
24 gible as described in clause (i) not later

1 than the applicable deadline for filing a pe-
 2 tition under such section 2116.

3 (B) REQUESTS INITIALLY SUBMITTED
 4 UNDER SECTION 2111.—

5 (i) IN GENERAL.—If a special master
 6 determines that—

7 (I) a petition submitted under
 8 section 2111 of the Public Health
 9 Service Act (42 U.S.C. 300aa–11) re-
 10 lated to a medical product for active
 11 immunization to prevent coronavirus
 12 disease 2019 that is ineligible for the
 13 program under subtitle 2 of title XXI
 14 of the Public Health Service Act (42
 15 U.S.C. 300aa–10 et seq.) because it
 16 relates to a medical product adminis-
 17 tered at a time when the medical
 18 product was not included in the table
 19 under section 2114 of such Act (42
 20 U.S.C. 300aa–14); and

21 (II) the medical product was ad-
 22 ministered when it was a covered
 23 countermeasure subject to a declara-
 24 tion under section 319F–3(b) of such
 25 Act (42 U.S.C. 247d–6d(b)),

1 the special master shall, not later than 30
2 days after such determination, notify the
3 petitioner of such determination.

4 (ii) SUBMISSION OF REQUEST.—An
5 individual who receives a notification de-
6 scribed in clause (i) shall be eligible to sub-
7 mit a request for compensation under sec-
8 tion 319F–4(b) of the Public Health Serv-
9 ice Act (42 U.S.C. 247d–6e(b)) with re-
10 spect to the same medical product adminis-
11 tration claimed in the petition submitted
12 under section 2111 of such Act (42 U.S.C.
13 300aa–11)—

14 (I) not later than 1 year after re-
15 ceiving such notification; or

16 (II) in the case that the notifica-
17 tion is issued after judicial review of
18 the petition under subsection (e) or
19 (f) of section 2112 of such Act (42
20 U.S.C. 300aa–12), not later than 1
21 year after the judgment of the United
22 States Court of Federal Claims or the
23 mandate is issued by the United
24 States Court of Appeals for the Fed-

1 eral Circuit pursuant to such sub-
2 section (e) or (f).

3 (iii) ELIGIBILITY.—To be eligible to
4 submit a request for compensation in ac-
5 cordance with clause (ii), the individual
6 submitting the request shall have sub-
7 mitted the petition under section 2111 of
8 the Public Health Service Act (42 U.S.C.
9 300aa–11) that was determined to be ineli-
10 gible not later than 1 year after the date
11 of administration of the medical product.

12 (2) CHANGES TO CERTAIN PROGRAMS.—

13 (A) SECTION 319F–4.—Section 319F–4 of
14 the Public Health Service Act (42 U.S.C.
15 247d–6e) is amended—

16 (i) in subsection (b)(4)—

17 (I) by striking “Except as pro-
18 vided” and inserting the following:

19 “(A) IN GENERAL.—Except as provided”;

20 and

21 (II) by adding at the end the fol-
22 lowing:

23 “(B) EXCLUSION OF INJURIES ELIGIBLE
24 FOR PETITION UNDER TITLE XXI.—Notwith-
25 standing any other provision of this section, no

individual may be eligible for compensation under this section with respect to a vaccine that, at the time it was administered, was included in the Vaccine Injury Table under section 2114.”; and

(ii) in subsection (d)(3)—

(I) by striking “This section”

and inserting the following:

“(A) IN GENERAL.—This section”; and

(II) by adding at the end the fol-

lowing:

“(B) EXHAUSTION OF REMEDIES.—A covered individual shall not be considered to have exhausted remedies as described in paragraph (1), nor be eligible to seek remedy under section 319F–3(d), unless such individual has provided to the Secretary all supporting documentation necessary to facilitate the determinations required under subsection (b)(4).”.

(B) TITLE XXI.—Title XXI of the Public Health Service Act (42 U.S.C. 300aa–1 et seq.) is amended—

(i) in section 2111(a)(2)(A) (42 U.S.C. 300aa–11(a)(2)(A)), in the matter preceding clause (i), by inserting “con-

1 taining the information required under
2 subsection (c)” after “unless a petition”;

3 (ii) in section 2112(d) (42 U.S.C.
4 300aa-12(d))—

5 (I) by adding at the end of para-
6 graph (1) the following: “Such des-
7 ignation shall not occur until the peti-
8 tioner has filed all materials required
9 under section 2111(c).”; and

10 (II) in paragraph (3)(A)(ii), by
11 striking “the petition was filed” and
12 inserting “on which the chief special
13 master makes the designation pursu-
14 ant to paragraph (1)”;

15 (iii) in section 2114(e) (42 U.S.C.
16 300aa-14(e)), by adding at the end the
17 following:

18 “(4) LICENSURE REQUIREMENT.—Notwith-
19 standing paragraphs (2) and (3), the Secretary may
20 not revise the Vaccine Injury Table to include a vac-
21 cine for which the Centers for Disease Control and
22 Prevention has issued a recommendation for routine
23 use in children or pregnant women until at least one
24 application for such vaccine has been approved
25 under section 351. Upon such revision of the Vac-

1 cine Injury Table, all vaccines in a vaccine category
 2 on the Vaccine Injury Table, including vaccines au-
 3 thorized under emergency use pursuant to section
 4 564 of the Federal Food, Drug, and Cosmetic Act,
 5 shall be considered included in the Vaccine Injury
 6 Table.”; and

7 (iv) in section 2116 (42 U.S.C.
 8 300aa–16), by adding at the end the fol-
 9 lowing:

10 “(d) CLARIFICATION.—Notwithstanding subsections
 11 (a) and (b), an injury or death related to a vaccine admin-
 12 istered at a time when the vaccine was a covered counter-
 13 measure subject to a declaration under section 319F–3(b)
 14 shall not be eligible for compensation under the Pro-
 15 gram.”.

16 (b) ACCELERATING INJURY COMPENSATION PRO-
 17 GRAM ADMINISTRATION AND ENSURING PROGRAM INTEG-
 18 RITY.—

19 (1) PETITIONS FOR COMPENSATION.—Section
 20 2111(a)(2)(A)(i) of the Public Health Service Act
 21 (42 U.S.C. 300aa–11(a)(2)(A)(i)) is amended—

22 (A) in subclause (I), by striking “, and”
 23 and inserting a semicolon;

24 (B) in subclause (II)—

1 (i) by moving the margin 2 ems to the
 2 right; and

3 (ii) by striking “, or” and inserting “;
 4 and”; and

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

6 “(III) the judgment described in subclause
 7 (I) does not result from a petitioner’s motion to
 8 dismiss the case; or”.

9 (2) DETERMINATION OF GOOD FAITH.—Section
 10 2115(e)(1) of the Public Health Service Act (42
 11 U.S.C. 300aa–15(e)(1)) is amended by adding at the
 12 end the following: “When making a determination of
 13 good faith under this paragraph, the special master
 14 or court may consider whether the petitioner dem-
 15 onstrated an intention to obtain compensation on
 16 such petition and was not merely seeking to satisfy
 17 the exhaustion requirement under section 2121(b).”.

18 (c) EXTENSION OF DEADLINES TO SUBMIT RE-
 19 QUESTS FOR COMPENSATION FOR CERTAIN INJURIES.—

20 (1) IN GENERAL.—With respect to claims filed
 21 under section 319F–4 of the Public Health Service
 22 Act (42 U.S.C. 247d–6e) alleging a covered injury
 23 caused by the administration or use of a covered
 24 countermeasure pursuant to a declaration under sec-
 25 tion 319F–3(b) of such Act (42 U.S.C. 247d–6d(b))

1 relating to coronavirus disease 2019, the following
2 shall apply:

3 (A) Notwithstanding the filing deadline ap-
4 plicable under such section 319F–4, the claim
5 shall be filed within 3 years of the administra-
6 tion or use of the covered countermeasure, or 1
7 year after the date of enactment of this Act,
8 whichever is later, and, if a claim filed under
9 such section 319F–4 with respect to such ad-
10 ministration or use was filed before the date of
11 enactment of this Act and denied on the basis
12 of having not been filed within the time period
13 required under subsection (b)(4) of such section
14 319F–4, such claim may be refiled pursuant to
15 this subparagraph.

16 (B) With respect to a claim relating to the
17 administration of a medical product for active
18 immunization to prevent coronavirus disease
19 2019 such a claim may be filed under the such
20 section 319F–4 only if the administration of
21 such vaccine occurred prior to the addition of
22 the vaccine to the Vaccine Injury Table under
23 section 2114 of the Public Health Service Act
24 (42 U.S.C. 300aa–14).

1 **SEC. 632. SUPPORTING AT-RISK INDIVIDUALS DURING**
2 **EMERGENCY RESPONSES.**

3 (a) TECHNICAL ASSISTANCE FOR AT-RISK INDIVID-
4 UALS AND DISASTERS.—

5 (1) IN GENERAL.—The Secretary of Health and
6 Human Services (referred to in this section as the
7 “Secretary”) may provide appropriate technical as-
8 sistance to States, localities, Tribes, and other appli-
9 cable entities related to addressing the unique needs
10 and considerations of at-risk individuals, as defined
11 in section 2802(b)(4) of the Public Health Service
12 Act (42 U.S.C. 300hh–1(b)(4)), in the event of a
13 public health emergency declared by the Secretary
14 pursuant to section 319 of the Public Health Service
15 Act (42 U.S.C. 247d).

16 (2) TECHNICAL ASSISTANCE.—The technical
17 assistance described in paragraph (1) shall include—

18 (A) developing, identifying, evaluating, and
19 disseminating evidence-based or evidence-in-
20 formed strategies to improve health and address
21 other near-term or long-term outcomes for at-
22 risk individuals related to public health emer-
23 gencies, including by addressing such unique
24 needs and considerations in carrying out public
25 health and medical activities to prepare for, re-

1 spond to, and recover from, such public health
2 emergencies; and

3 (B) assisting applicable entities, through
4 contracts or cooperative agreements, as appro-
5 priate, in the implementation of such evidence-
6 based strategies.

7 (3) CONSULTATION.—In carrying out activities
8 under paragraph (2), the Secretary shall take into
9 consideration relevant findings and recommendations
10 of, and, as appropriate, consult with, the National
11 Advisory Committee on Individuals with Disabilities
12 and Disasters established under section 2811C of
13 the Public Health Service Act (42 U.S.C. 300hh–
14 10d), the National Advisory Committee on Children
15 and Disasters under section 2811A of such Act (42
16 U.S.C. 300hh–10b), and the National Advisory
17 Committee on Seniors and Disasters under section
18 2811B of such Act (42 U.S.C. 300hh–10c).

19 (b) CRISIS STANDARDS OF CARE.—Not later than 2
20 years after the date of enactment of this Act, the Sec-
21 retary, acting through the Director of the Office for Civil
22 Rights of the Department of Health and Human Services,
23 shall issue guidance to States and localities on the develop-
24 ment or modification of State and local crisis standards
25 of care for use during the response to a public health

1 emergency declared by the Governor of a State or by the
 2 Secretary under section 319 of the Public Health Service
 3 Act (42 U.S.C. 247d), or a major disaster or emergency
 4 declared by the President under section 401 or 501, re-
 5 spectively, of the Robert T. Stafford Disaster Relief and
 6 Emergency Assistance Act (42 U.S.C. 5170, 5191) to en-
 7 sure that such standards of care are consistent with the
 8 nondiscrimination requirements of section 504 of the Re-
 9 habilitation Act of 1973 (29 U.S.C. 794), title II of the
 10 Americans with Disabilities Act of 1990 (42 U.S.C. 12131
 11 et seq.), and the Age Discrimination Act of 1975 (42
 12 U.S.C. 6101 et seq.).

13 **SEC. 633. NATIONAL ADVISORY COMMITTEES.**

14 (a) NATIONAL ADVISORY COMMITTEE ON CHILDREN
 15 AND DISASTERS.—Subsection (g) of section 2811A of the
 16 Public Health Service Act (42 U.S.C. 300hh–10b) is
 17 amended to read as follows:

18 “(g) SUNSET.—

19 “(1) IN GENERAL.—The Advisory Committee
 20 shall terminate on December 31, 2026.

21 “(2) EXTENSION OF ADVISORY COMMITTEE.—

22 Not later than October 1, 2025, the Secretary shall
 23 submit to Congress a recommendation on whether
 24 the Advisory Committee should be extended beyond
 25 the date described in paragraph (1).”.

1 (b) NATIONAL ADVISORY COMMITTEE ON SENIORS
 2 AND DISASTERS.—Section 2811B of the Public Health
 3 Service Act (42 U.S.C. 300hh–10c) is amended—

4 (1) in subsection (d)—

5 (A) in paragraph (1)—

6 (i) by inserting “and departments”
 7 after “agencies”; and

8 (ii) by striking “17 members” and in-
 9 serting “25 members”; and

10 (B) in paragraph (2)—

11 (i) by striking subparagraphs (J) and
 12 (K);

13 (ii) by redesignating subparagraphs
 14 (A) through (I) and (L) as clauses (i)
 15 through (x), respectively, and adjusting the
 16 margins accordingly;

17 (iii) by inserting before clause (i), as
 18 so redesignated, the following:

19 “(B) FEDERAL MEMBERS.—The Federal
 20 members shall include the following.”; and

21 (iv) by inserting before subparagraph
 22 (B), as so designated, the following:

23 “(A) NON-FEDERAL MEMBERS.—The Sec-
 24 retary in consultation with such other heads of
 25 agencies and departments as may be appro-

priate, shall appoint to the Advisory Committee under paragraph (1) at least 13 individuals, including the following:

“(i) At least 3 non-Federal health care providers with expertise in geriatric medical disaster planning, preparedness, response, or recovery.

“(ii) At least 3 representatives of State, local, territorial, or Tribal agencies with expertise in geriatric disaster planning, preparedness, response, or recovery.

“(iii) At least 2 non-Federal professionals with training in gerontology, such as social workers, scientists, human services specialists, or other non-medical professionals, with experience in disaster planning, preparedness, response, or recovery among other adults.”; and

(2) by amending subsection (g) to read as follows:

“(g) SUNSET.—The Advisory Committee shall terminate on December 31, 2026.”.

(c) NATIONAL ADVISORY COMMITTEE ON INDIVIDUALS WITH DISABILITIES AND DISASTERS.—Section

1 2811C of the Public Health Service Act (42 U.S.C.
2 300hh–10d) is amended—

3 (1) by redesignating subsections (c) through (g)
4 as subsections (d) through (h), respectively;

5 (2) by inserting after subsection (b) the fol-
6 lowing:

7 “(c) ADDITIONAL DUTIES.—The Advisory Committee
8 may provide advice and recommendations to the Secretary
9 with respect to individuals with disabilities and the med-
10 ical and public health grants and cooperative agreements
11 as applicable to preparedness and response activities
12 under this title and title III.”;

13 (3) in subsection (d), as so redesignated—

14 (A) in paragraph (1), by striking “17
15 members” and inserting “25 members”;

16 (B) in paragraph (2)—

17 (i) by striking subparagraphs (K)
18 through (M);

19 (ii) by redesignating subparagraphs
20 (A) through (J) as clauses (i) through (x),
21 respectively, and adjusting the margins ac-
22 cordingly;

23 (iii) by inserting before clause (i), as
24 so redesignated, the following:

1 “(B) FEDERAL MEMBERS.—The Federal
2 members shall include the following.”;

3 (iv) by adding at the end of subpara-
4 graph (B), as so designated, the following:

5 “(xi) Representatives of such other
6 Federal agencies as the Secretary deter-
7 mines necessary to fulfill the duties of the
8 Advisory Committee.”; and

9 (v) by inserting before subparagraph
10 (B), as so designated, the following:

11 “(A) NON-FEDERAL MEMBERS.—The Sec-
12 retary in consultation with such other heads of
13 agencies and departments as may be appro-
14 priate, shall appoint to the Advisory Committee
15 under paragraph (1) at least 13 individuals, in-
16 cluding the following:

17 “(i) At least 4 non-Federal health
18 care professionals with expertise in dis-
19 ability accessibility before, during, and
20 after disasters, medical and mass care dis-
21 aster planning, preparedness, response, or
22 recovery.

23 “(ii) At least 3 representatives of
24 State, local, Tribal, or territorial agencies
25 with expertise in disaster planning, pre-

paredness, response, or recovery for individuals with disabilities.

“(iii) At least 4 individuals with a disability with expertise in disaster planning, preparedness, response, or recovery for individuals with disabilities.

“(iv) Other members as the Secretary determines appropriate, of whom—

“(I) at least one such member shall represent a local, State, or national organization with expertise in individuals with disabilities;

“(II) at least one such member shall be an individual with a disability; and

“(III) at least one such member shall be an individual with expertise in the needs of housing services, including during the response to, and recovery from, disasters.”; and

(C) by adding at the end the following:

“(3) CONSIDERATION.—In appointing members, including the Chair, to the Committee under this subsection, the Secretary may give consideration to disability status.”; and

1 (4) by amending subsection (h), as so redesign-
 2 nated, to read as follows:

3 “(h) SUNSET.—The Advisory Committee shall termi-
 4 nate on December 31, 2026.”.

5 **SEC. 634. NATIONAL ACADEMIES STUDY ON PRIZES.**

6 (a) IN GENERAL.—Not later than 90 days after the
 7 date of enactment of this Act, the Secretary of Health and
 8 Human Services shall seek to enter into an agreement
 9 with the National Academies of Sciences, Engineering,
 10 and Medicine (referred to in this section as the “National
 11 Academies”) to conduct a study to examine—

12 (1) alternative models for directly funding, or
 13 stimulating investment in, biomedical research and
 14 development that delink research and development
 15 costs from the prices of drugs, including the pro-
 16 gressive replacement of patents and regulatory
 17 exclusivities on new drugs with a combination of ex-
 18 panded support for research and innovation prizes to
 19 reward the successful development of drugs or
 20 achievement of related milestones;

21 (2) the dollar amount of innovation prizes for
 22 different stages of research and development of dif-
 23 ferent classes or types of drugs, and total annual
 24 funding, that would be necessary to stimulate invest-

1 ment sufficient to achieve such successful drug de-
2 velopment and related milestones;

3 (3) the relative effectiveness and efficiency of
4 such alternative models in stimulating innovation,
5 compared to the status quo that includes patents
6 and regulatory exclusivities;

7 (4) strategies to implement such alternative
8 models described in paragraph (1), including a
9 phased transition; and

10 (5) the anticipated economic and societal im-
11 pacts of such alternative models, including an as-
12 sessment of impact on—

13 (A) the number and variety of new drugs
14 that would be developed, approved, and mar-
15 keted in the United States, including such new
16 drugs intended to prevent, diagnose, or treat a
17 rare disease or condition;

18 (B) the rate at which new drugs would be
19 developed, approved, and marketed in the
20 United States;

21 (C) access to medication;

22 (D) health outcomes;

23 (E) average lifespan and disease burden in
24 the United States;

1 (F) the number of manufacturers that
2 would be seeking approval for a drug or bring-
3 ing a drug to market for the first time;

4 (G) Federal discretionary and mandatory
5 spending; and

6 (H) public and private insurance markets.

7 (b) REQUIREMENTS.—In conducting the study pursu-
8 ant to subsection (a), the National Academies shall hold
9 not fewer than 2 public listening sessions to solicit feed-
10 back from interested parties, including representatives of
11 academia, professional societies, patient advocates, public
12 health organizations, relevant Federal departments and
13 agencies, drug developers, representatives of other rel-
14 evant industries, and subject matter experts.

15 (c) REPORT.—Not later than 2 years after the agree-
16 ment under subsection (a), the National Academies shall
17 submit to the Committee on Health, Education, Labor,
18 and Pensions and the Committee on Appropriations of the
19 Senate and the Committee on Energy and Commerce and
20 the Committee on Appropriations of the House of Rep-
21 resentatives a report on the study conducted pursuant to
22 subsection (a).

Subtitle D—Additional Reauthorizations

SEC. 641. MEDICAL COUNTERMEASURE PRIORITY REVIEW VOUCHER.

Section 565A(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4a) is amended by striking “October 1, 2023” and inserting “December 31, 2026”.

SEC. 642. EPIDEMIC INTELLIGENCE SERVICE.

Section 317F(c)(2) of the Public Health Service Act (42 U.S.C. 247b–7(c)(2)) is amended by striking “2019 through 2023” and inserting “2025 and 2026, to remain available through December 31, 2026”.

SEC. 643. MONITORING AND DISTRIBUTION OF CERTAIN MEDICAL COUNTERMEASURES.

Section 319A(e) of the Public Health Service Act (42 U.S.C. 247d–1(e)) is amended by striking “2019 through 2023” and inserting “2025 and 2026, to remain available through December 31, 2026”.

SEC. 644. REGIONAL HEALTH CARE EMERGENCY PREPAREDNESS AND RESPONSE SYSTEMS.

Section 319C–3 of the Public Health Service Act (42 U.S.C. 247d–3c) is amended—

(1) in subsection (b)(3), by striking “under the” and all that follows through “such Act)” and inserting “under law”; and

1 (2) in subsection (e)(2), by striking “September
2 30, 2023” and inserting “December 31, 2026”.

3 **SEC. 645. EMERGENCY SYSTEM FOR ADVANCE REGISTRA-**
4 **TION OF VOLUNTEER HEALTH PROFES-**
5 **SIONALS.**

6 (1) IN GENERAL.—Section 319I of the Public
7 Health Service Act (42 U.S.C. 247d–7b) is amend-
8 ed—

9 (A) in subsection (a), by striking “Not
10 later than 12 months after the date of enact-
11 ment of the Pandemic and All-Hazards Pre-
12 paredness Act, the Secretary shall link existing
13 State verification systems to maintain a single
14 national interoperable network of systems,” and
15 inserting “The Secretary shall continue to
16 maintain a single national interoperable net-
17 work of verification systems,” and

18 (B) in subsection (k), by striking “2019
19 through 2023” and inserting “2025 and 2026,
20 to remain available through December 31,
21 2026”.

1 **SEC. 646. ENSURING COLLABORATION AND COORDINATION**
2 **IN MEDICAL COUNTERMEASURE DEVELOP-**
3 **MENT.**

4 Section 319L–1(b) of the Public Health Service Act
5 (42 U.S.C. 247d–7f(b)) is amended by striking “March
6 31, 2025” and inserting “December 31, 2026”.

7 **SEC. 647. MILITARY AND CIVILIAN PARTNERSHIP FOR**
8 **TRAUMA READINESS.**

9 Section 1291(g) of the Public Health Service Act (42
10 U.S.C. 300d–91(g)) is amended by striking “2019
11 through 2023” and inserting “2025 and 2026, to remain
12 available through December 31, 2026”.

13 **SEC. 648. NATIONAL DISASTER MEDICAL SYSTEM.**

14 Section 2812 of the Public Health Service Act (42
15 U.S.C. 300hh–11) is amended—

16 (1) in subsection (c)(4)(B), by striking “March
17 31, 2025” and inserting “December 31, 2026”; and

18 (2) in subsection (g), by striking “\$57,400,000
19 for each of fiscal years 2019 through 2023” and in-
20 serting “\$65,900,000 for each of fiscal years 2025
21 and 2026, to remain available through December 31,
22 2026”.

23 **SEC. 649. VOLUNTEER MEDICAL RESERVE CORPS.**

24 Section 2813(i) of the Public Health Service Act (42
25 U.S.C. 300hh–15(i)) is amended by striking “2019

1 through 2023” and inserting “2025 through 2026, to re-
 2 main available through December 31, 2026”.

3 **SEC. 649A. EPIDEMIOLOGY-LABORATORY CAPACITY.**

4 Section 2821(b) of the Public Health Service Act (42
 5 U.S.C. 300hh–31(b)) is amended, in the matter preceding
 6 paragraph (1), by striking “2019 through 2023” and in-
 7 serting “2025 and 2026, to remain available through De-
 8 cember 31, 2026”.

9 **TITLE VII—PUBLIC HEALTH**
 10 **PROGRAMS**

11 **SEC. 701. ACTION FOR DENTAL HEALTH.**

12 Section 340G(f) of the Public Health Service Act (42
 13 U.S.C. 256g(f)) is amended by striking “\$13,903,000 for
 14 each of fiscal years 2019 through 2023” and inserting
 15 “\$15,000,000 for each of fiscal years 2025 through 2029,
 16 to remain available until expended”.

17 **SEC. 702. PREEMIE.**

18 (a) RESEARCH RELATING TO PRETERM LABOR AND
 19 DELIVERY AND THE CARE, TREATMENT, AND OUTCOMES
 20 OF PRETERM AND LOW BIRTHWEIGHT INFANTS.—

21 (1) IN GENERAL.—Section 3(e) of the Pre-
 22 maturity Research Expansion and Education for
 23 Mothers who deliver Infants Early Act (42 U.S.C.
 24 247b–4f(e)) is amended by striking “fiscal years

1 2019 through 2023” and inserting “fiscal years
2 2025 through 2029”.

3 (2) TECHNICAL CORRECTION.—Effective as if
4 included in the enactment of the PREEMIE Reau-
5 thorization Act of 2018 (Public Law 115–328), sec-
6 tion 2 of such Act is amended, in the matter pre-
7 ceding paragraph (1), by striking “Section 2” and
8 inserting “Section 3”.

9 (b) INTERAGENCY WORKING GROUP.—Section 5(a)
10 of the PREEMIE Reauthorization Act of 2018 (Public
11 Law 115–328) is amended by striking “The Secretary of
12 Health and Human Services, in collaboration with other
13 departments, as appropriate, may establish” and inserting
14 “Not later than 18 months after the date of the enactment
15 of the Bipartisan Health Care Act, the Secretary of
16 Health and Human Services, in collaboration with other
17 departments, as appropriate, shall establish”.

18 (c) STUDY ON PRETERM BIRTHS.—

19 (1) IN GENERAL.—The Secretary of Health and
20 Human Services shall enter into appropriate ar-
21 rangements with the National Academies of
22 Sciences, Engineering, and Medicine under which
23 the National Academies shall—

24 (A) not later than 30 days after the date
25 of enactment of this Act, convene a committee

1 of experts in maternal health to study pre-
2 mature births in the United States; and

3 (B) upon completion of the study under
4 subparagraph (A)—

5 (i) approve by consensus a report on
6 the results of such study;

7 (ii) include in such report—

8 (I) an assessment of each of the
9 topics listed in paragraph (2);

10 (II) the analysis required by
11 paragraph (3); and

12 (III) the raw data used to de-
13 velop such report; and

14 (iii) not later than 24 months after
15 the date of enactment of this Act, transmit
16 such report to—

17 (I) the Secretary of Health and
18 Human Services;

19 (II) the Committee on Energy
20 and Commerce of the House of Rep-
21 resentatives; and

22 (III) the Committee on Finance
23 and the Committee on Health, Edu-
24 cation, Labor, and Pensions of the
25 Senate.

(2) ASSESSMENT TOPICS.—The topics listed in this subsection are each of the following:

(A) The financial costs of premature birth to society, including—

(i) an analysis of stays in neonatal intensive care units and the cost of such stays;

(ii) long-term costs of stays in such units to society and the family involved post-discharge; and

(iii) health care costs for families post-discharge from such units (such as medications, therapeutic services, co-payments for visits, and specialty equipment).

(B) The factors that impact preterm birth rates.

(C) Opportunities for earlier detection of premature birth risk factors, including—

(i) opportunities to improve maternal and infant health; and

(ii) opportunities for public health programs to provide support and resources for parents in-hospital, in non-hospital settings, and post-discharge.

1 (3) ANALYSIS.—The analysis required by this
2 subsection is an analysis of—

3 (A) targeted research strategies to develop
4 effective drugs, treatments, or interventions to
5 bring at-risk pregnancies to term;

6 (B) State and other programs’ best prac-
7 tices with respect to reducing premature birth
8 rates; and

9 (C) precision medicine and preventative
10 care approaches starting early in the life course
11 (including during pregnancy) with a focus on
12 behavioral and biological influences on pre-
13 mature birth, child health, and the trajectory of
14 such approaches into adulthood.

15 **SEC. 703. PREVENTING MATERNAL DEATHS.**

16 (a) MATERNAL MORTALITY REVIEW COMMITTEE.—
17 Section 317K(d) of the Public Health Service Act (42
18 U.S.C. 247b–12(d)) is amended—

19 (1) in paragraph (1)(A), by inserting “(includ-
20 ing obstetricians and gynecologists)” after “clinical
21 specialties”; and

22 (2) in paragraph (3)(A)(i)—

23 (A) in subclause (I), by striking “as appli-
24 cable” and inserting “if available”; and

1 (B) in subclause (III), by striking “, as ap-
 2 propriate” and inserting “and coordinating with
 3 death certifiers to improve the collection of
 4 death record reports and the quality of death
 5 records, including by amending cause of death
 6 information on a death certificate, as appro-
 7 priate”.

8 (b) BEST PRACTICES RELATING TO THE PREVEN-
 9 TION OF MATERNAL MORTALITY.—Section 317K of the
 10 Public Health Service Act (42 U.S.C. 247b–12) is amend-
 11 ed—

12 (1) by redesignating subsections (e) and (f) as
 13 subsections (f) and (g), respectively; and

14 (2) by inserting after subsection (d) the fol-
 15 lowing:

16 “(e) BEST PRACTICES RELATING TO THE PREVEN-
 17 TION OF MATERNAL MORTALITY.—

18 “(1) IN GENERAL.—The Secretary, acting
 19 through the Director of the Centers for Disease
 20 Control and Prevention, shall, in consultation with
 21 the Administrator of the Health Resources and Serv-
 22 ices Administration, disseminate to hospitals, State
 23 professional society groups, and perinatal quality
 24 collaboratives, best practices on how to prevent ma-
 25 ternal mortality and morbidity that consider and re-

1 flect best practices identified through other relevant
2 Federal maternal health programs.

3 “(2) FREQUENCY.—The Secretary, acting
4 through the Director of the Centers for Disease
5 Control and Prevention, shall disseminate the best
6 practices referred to in paragraph (1) not less than
7 once per fiscal year.”.

8 (c) EXTENSION.—Subsection (g) of section 317K of
9 the Public Health Service Act (42 U.S.C. 247b–12), as
10 redesignated by subsection (b), is amended by striking
11 “\$58,000,000 for each of fiscal years 2019 through 2023”
12 and inserting “\$100,000,000 for each of fiscal years 2025
13 through 2029”.

14 **SEC. 704. SICKLE CELL DISEASE PREVENTION AND TREAT-**
15 **MENT.**

16 (a) IN GENERAL.—Section 1106(b) of the Public
17 Health Service Act (42 U.S.C. 300b–5(b)) is amended—

18 (1) in paragraph (1)(A)(iii), by striking “pre-
19 vention and treatment of sickle cell disease” and in-
20 serting “treatment of sickle cell disease and the pre-
21 vention and treatment of complications of sickle cell
22 disease”;

23 (2) in paragraph (2)(D), by striking “preven-
24 tion and treatment of sickle cell disease” and insert-
25 ing “treatment of sickle cell disease and the preven-

1 tion and treatment of complications of sickle cell dis-
2 ease”;

3 (3) in paragraph (3)—

4 (A) in subparagraph (A), by striking
5 “enter into a contract with” and inserting
6 “make a grant to, or enter into a contract or
7 cooperative agreement with,”; and

8 (B) in subparagraph (B), in each of
9 clauses (ii) and (iii), by striking “prevention
10 and treatment of sickle cell disease” and insert-
11 ing “treatment of sickle cell disease and the
12 prevention and treatment of complications of
13 sickle cell disease”; and

14 (4) in paragraph (6), by striking “\$4,455,000
15 for each of fiscal years 2019 through 2023” and in-
16 serting “\$8,205,000 for each of fiscal years 2025
17 through 2029”.

18 (b) SENSE OF CONGRESS.—It is the sense of Con-
19 gress that further research should be undertaken to ex-
20 pand the understanding of the causes of, and to find cures
21 for, heritable blood disorders, including sickle cell disease.

22 **SEC. 705. TRAUMATIC BRAIN INJURIES.**

23 (a) THE BILL PASCRELL, JR., NATIONAL PROGRAM
24 FOR TRAUMATIC BRAIN INJURY SURVEILLANCE AND
25 REGISTRIES.—

1 (1) PREVENTION OF TRAUMATIC BRAIN IN-
2 JURY.—Section 393B of the Public Health Service
3 Act (42 U.S.C. 280b–1c) is amended—

4 (A) in subsection (a), by inserting “and
5 prevalence” after “incidence”;

6 (B) in subsection (b)—

7 (i) in paragraph (1), by inserting
8 “and reduction of associated injuries and
9 fatalities” before the semicolon;

10 (ii) in paragraph (2), by inserting
11 “and related risk factors” before the semi-
12 colon; and

13 (iii) in paragraph (3)—

14 (I) in the matter preceding sub-
15 paragraph (A), by striking “2020”
16 each place it appears and inserting
17 “2030”; and

18 (II) in subparagraph (A)—

19 (aa) in clause (i), by striking
20 “; and” and inserting a semi-
21 colon;

22 (bb) by redesignating clause
23 (ii) as clause (iv);

24 (cc) by inserting after clause
25 (i) the following:

1 “(ii) populations at higher risk of
 2 traumatic brain injury, including popu-
 3 lations whose increased risk is due to occu-
 4 pational or circumstantial factors;

5 “(iii) causes of, and risk factors for,
 6 traumatic brain injury; and”; and

7 (dd) in clause (iv), as so re-
 8 designated, by striking “arising
 9 from traumatic brain injury” and
 10 inserting “, which may include
 11 related mental health and other
 12 conditions, arising from trau-
 13 matic brain injury, including”;
 14 and

15 (C) in subsection (c), by inserting “, and
 16 other relevant Federal departments and agen-
 17 cies” before the period at the end.

18 (2) NATIONAL PROGRAM FOR TRAUMATIC
 19 BRAIN INJURY SURVEILLANCE AND REGISTRIES.—
 20 Section 393C of the Public Health Service Act (42
 21 U.S.C. 280b–1d) is amended—

22 (A) by amending the section heading to
 23 read as follows: “**THE BILL PASCRELL, JR.,**
 24 **NATIONAL PROGRAM FOR TRAUMATIC**

**BRAIN INJURY SURVEILLANCE AND REG-
ISTRIES”;**

(B) in subsection (a)—

(i) in the matter preceding paragraph (1), by inserting “to identify populations that may be at higher risk for traumatic brain injuries, to collect data on the causes of, and risk factors for, traumatic brain injuries,” after “related disability,”;

(ii) in paragraph (1), by inserting “, including the occupation of the individual, when relevant to the circumstances surrounding the injury” before the semicolon; and

(iii) in paragraph (4), by inserting “short- and long-term” before “outcomes”;

(C) by striking subsection (b);

(D) by redesignating subsection (c) as subsection (b);

(E) in subsection (b), as so redesignated, by inserting “and evidence-based practices to identify and address concussion” before the period at the end; and

(F) by adding at the end the following:

1 “(c) AVAILABILITY OF INFORMATION.—The Sec-
 2 retary, acting through the Director of the Centers for Dis-
 3 ease Control and Prevention, shall make publicly available
 4 aggregated information on traumatic brain injury and
 5 concussion described in this section, including on the
 6 website of the Centers for Disease Control and Prevention.
 7 Such website, to the extent feasible, shall include aggre-
 8 gated information on populations that may be at higher
 9 risk for traumatic brain injuries and strategies for pre-
 10 venting or reducing risk of traumatic brain injury that are
 11 tailored to such populations.”.

12 (3) AUTHORIZATION OF APPROPRIATIONS.—
 13 Section 394A of the Public Health Service Act (42
 14 U.S.C. 280b–3) is amended—

15 (A) in subsection (a), by striking “1994,
 16 and” and inserting “1994,”; and

17 (B) in subsection (b), by striking “2020
 18 through 2024” and inserting “2025 through
 19 2029”.

20 (b) STATE GRANT PROGRAMS.—

21 (1) STATE GRANTS FOR PROJECTS REGARDING
 22 TRAUMATIC BRAIN INJURY.—Section 1252 of the
 23 Public Health Service Act (42 U.S.C. 300d–52) is
 24 amended—

25 (A) in subsection (b)(2)—

1 (i) by inserting “, taking into consid-
2 eration populations that may be at higher
3 risk for traumatic brain injuries” after
4 “outreach programs”; and

5 (ii) by inserting “Tribal,” after
6 “State,”;

7 (B) in subsection (c), by adding at the end
8 the following:

9 “(3) MAINTENANCE OF EFFORT.—With respect
10 to activities for which a grant awarded under sub-
11 section (a) is to be expended, a State or American
12 Indian consortium shall agree to maintain expendi-
13 tures of non-Federal amounts for such activities at
14 a level that is not less than the level of such expendi-
15 tures maintained by the State or American Indian
16 consortium for the fiscal year preceding the fiscal
17 year for which the State or American Indian consor-
18 tium receives such a grant.

19 “(4) WAIVER.—The Secretary may, upon the
20 request of a State or American Indian consortium,
21 waive not more than 50 percent of the matching
22 fund amount under paragraph (1), if the Secretary
23 determines that such matching fund amount would
24 result in an inability of the State or American In-
25 dian consortium to carry out the purposes under

subsection (a). A waiver provided by the Secretary under this paragraph shall apply only to the fiscal year involved.”;

(C) in subsection (e)(3)(B)—

(i) by striking “(such as third party payers, State agencies, community-based providers, schools, and educators)”;

(ii) by inserting “(such as third party payers, State agencies, community-based providers, schools, and educators)” after “professionals”;

(D) in subsection (h), by striking paragraphs (1) and (2) and inserting the following:

“(1) AMERICAN INDIAN CONSORTIUM; STATE.—

The terms ‘American Indian consortium’ and ‘State’ have the meanings given such terms in section 1253.

“(2) TRAUMATIC BRAIN INJURY.—

“(A) IN GENERAL.—Subject to subparagraph (B), the term ‘traumatic brain injury’—

“(i) means an acquired injury to the brain;

“(ii) may include—

“(I) brain injuries caused by anoxia due to trauma; and

1 “(II) damage to the brain from
 2 an internal or external source that re-
 3 sults in infection, toxicity, surgery, or
 4 vascular disorders not associated with
 5 aging; and

6 “(iii) does not include brain dysfunc-
 7 tion caused by congenital or degenerative
 8 disorders, or birth trauma.

9 “(B) REVISIONS TO DEFINITION.—The
 10 Secretary may revise the definition of the term
 11 ‘traumatic brain injury’ under this paragraph,
 12 as the Secretary determines necessary, after
 13 consultation with States and other appropriate
 14 public or nonprofit private entities.”; and

15 (E) in subsection (i), by striking “2020
 16 through 2024” and inserting “2025 through
 17 2029”.

18 (2) STATE GRANTS FOR PROTECTION AND AD-
 19 VOCACY SERVICES.—Section 1253(l) of the Public
 20 Health Service Act (42 U.S.C. 300d–53(l)) is
 21 amended by striking “2020 through 2024” and in-
 22 serting “2025 through 2029”.

23 (c) REPORT TO CONGRESS.—Not later than 2 years
 24 after the date of enactment of this Act, the Secretary of
 25 Health and Human Services (referred to in this Act as

1 the “Secretary”) shall submit to the Committee on
2 Health, Education, Labor, and Pensions of the Senate and
3 the Committee on Energy and Commerce of the House
4 of Representatives a report that contains—

5 (1) an overview of populations who may be at
6 higher risk for traumatic brain injury, such as indi-
7 viduals affected by domestic violence or sexual as-
8 sault and public safety officers as defined in section
9 1204 of the Omnibus Crime Control and Safe
10 Streets Act of 1968 (34 U.S.C. 10284);

11 (2) an outline of existing surveys and activities
12 of the Centers for Disease Control and Prevention
13 on traumatic brain injuries and any steps the agency
14 has taken to address gaps in data collection related
15 to such higher risk populations, which may include
16 leveraging surveys such as the National Intimate
17 Partner and Sexual Violence Survey to collect data
18 on traumatic brain injuries;

19 (3) an overview of any outreach or education ef-
20 forts to reach such higher risk populations; and

21 (4) any challenges associated with reaching
22 such higher risk populations.

23 (d) STUDY ON LONG-TERM SYMPTOMS OR CONDI-
24 TIONS RELATED TO TRAUMATIC BRAIN INJURY.—

1 (1) IN GENERAL.—The Secretary, in consulta-
2 tion with stakeholders and the heads of other rel-
3 evant Federal departments and agencies, as appro-
4 priate, shall conduct, either directly or through a
5 contract with a nonprofit private entity, a study to—

6 (A) examine the incidence and prevalence
7 of long-term or chronic symptoms or conditions
8 in individuals who have experienced a traumatic
9 brain injury;

10 (B) examine the evidence base of research
11 related to the chronic effects of traumatic brain
12 injury across the lifespan;

13 (C) examine any correlations between trau-
14 matic brain injury and increased risk of other
15 conditions, such as dementia and mental health
16 conditions;

17 (D) assess existing services available for
18 individuals with such long-term or chronic
19 symptoms or conditions; and

20 (E) identify any gaps in research related to
21 such long-term or chronic symptoms or condi-
22 tions of individuals who have experienced a
23 traumatic brain injury.

1 (2) PUBLIC REPORT.—Not later than 2 years
2 after the date of enactment of this Act, the Sec-
3 retary shall—

4 (A) submit to the Committee on Energy
5 and Commerce of the House of Representatives
6 and the Committee on Health, Education,
7 Labor, and Pensions of the Senate a report de-
8 tailing the findings, conclusions, and rec-
9 ommendations of the study described in para-
10 graph (1); and

11 (B) in the case that such study is con-
12 ducted directly by the Secretary, make the re-
13 port described in subparagraph (A) publicly
14 available on the website of the Department of
15 Health and Human Services.

16 **SEC. 706. LIFESPAN RESPITE CARE.**

17 (a) DEFINITION OF FAMILY CAREGIVER.—Section
18 2901(5) of the Public Health Service Act (42 U.S.C.
19 300ii(5)) is amended by striking “unpaid adult” and in-
20 serting “unpaid individual”.

21 (b) FUNDING.—Section 2905 of the Public Health
22 Service Act (42 U.S.C. 300ii–4) is amended by striking
23 “fiscal years 2020 through fiscal year 2024” and inserting
24 “fiscal years 2025 through 2029”.

1 **SEC. 707. DR. LORNA BREEN HEALTH CARE PROVIDER PRO-**
2 **TECTION.**

3 (a) DISSEMINATION OF BEST PRACTICES.— Section
4 2 of the Dr. Lorna Breen Health Care Provider Protection
5 Act (Public Law 117–105) is amended by striking “2
6 years” and inserting “5 years”.

7 (b) EDUCATION AND AWARENESS INITIATIVE EN-
8 COURAGING USE OF MENTAL HEALTH AND SUBSTANCE
9 USE DISORDER SERVICES BY HEALTH CARE PROFES-
10 SIONALS.—Section 3 of the Dr. Lorna Breen Health Care
11 Provider Protection Act (Public Law 117–105) is amend-
12 ed—

13 (1) in subsection (b), by inserting “and annu-
14 ally thereafter,” after “of this Act,”; and

15 (2) in subsection (c), by striking “2022 through
16 2024” and inserting “2025 through 2029”.

17 (c) PROGRAMS TO PROMOTE MENTAL HEALTH
18 AMONG THE HEALTH PROFESSIONAL WORKFORCE.—The
19 second section 764 of the Public Health Service Act (42
20 U.S.C. 294t), as added by section 4 of the Dr. Lorna
21 Breen Health Care Provider Protection Act (Public Law
22 117–105), is amended—

23 (1) by redesignating such section 764 as section
24 764A;

25 (2) in subsection (a)(3)—

- 1 (A) by striking “to eligible entities in” and
- 2 inserting “to eligible entities that—
- 3 “(A) are in”;
- 4 (B) by striking the period and inserting “;
- 5 or”; and
- 6 (C) by adding at the end the following:
- 7 “(B) have a focus on the reduction of ad-
- 8 ministrative burden on health care workers.”;
- 9 (3) in subsection (c), by inserting “not less
- 10 than” after “period of”; and
- 11 (4) in subsection (f), by striking “2022 through
- 12 2024” and inserting “2025 through 2029”.

13 **SEC. 708. SCREENS FOR CANCER.**

14 (a) NATIONAL BREAST AND CERVICAL CANCER
 15 EARLY DETECTION PROGRAM.—Title XV of the Public
 16 Health Service Act (42 U.S.C. 300k et seq.) is amended—

- 17 (1) in section 1501 (42 U.S.C. 300k)—
- 18 (A) in subsection (a)—
- 19 (i) in paragraph (2), by striking “the
- 20 provision of appropriate follow-up services
- 21 and support services such as case manage-
- 22 ment” and inserting “that appropriate fol-
- 23 low-up services are provided”;
- 24 (ii) in paragraph (3), by striking
- 25 “programs for the detection and control”

1 and inserting “for the prevention, detec-
 2 tion, and control”;

3 (iii) in paragraph (4), by striking “the
 4 detection and control” and inserting “the
 5 prevention, detection, and control”;

6 (iv) in paragraph (5)—

7 (I) by striking “monitor” and in-
 8 serting “ensure”; and

9 (II) by striking “; and” and in-
 10 serting a semicolon;

11 (v) by redesignating paragraph (6) as
 12 paragraph (9);

13 (vi) by inserting after paragraph (5)
 14 the following:

15 “(6) to enhance appropriate support activities
 16 to increase breast and cervical cancer screenings,
 17 such as navigation of health care services, implemen-
 18 tation of evidence-based or evidence-informed strate-
 19 gies to increase breast and cervical cancer screening
 20 in health care settings, and facilitation of access to
 21 health care settings;

22 “(7) to reduce disparities in breast and cervical
 23 cancer incidence, morbidity, and mortality, including
 24 in populations with higher than average rates;

1 “(8) to improve access to breast and cervical
2 cancer screening and diagnostic services and reduce
3 related barriers, including factors that relate to neg-
4 ative health outcomes; and”; and

5 (vii) in paragraph (9), as so redesign-
6 nated, by striking “through (5)” and in-
7 serting “through (8)”; and

8 (B) by striking subsection (d);

9 (2) in section 1503 (42 U.S.C. 300m)—

10 (A) in subsection (a)—

11 (i) in paragraph (1), by striking
12 “that, initially” and all that follows
13 through the semicolon and inserting “that
14 appropriate breast and cervical cancer
15 screening and diagnostic services are pro-
16 vided consistent with relevant evidence-
17 based recommendations; and”;

18 (ii) by striking paragraphs (2) and
19 (4);

20 (iii) by redesignating paragraph (3) as
21 paragraph (2); and

22 (iv) in paragraph (2), as so redesign-
23 nated, by striking “; and” and inserting a
24 period; and

25 (B) by striking subsection (d);

1 (3) in section 1508(b) (42 U.S.C. 300n-4(b))—

2 (A) by striking “1 year after the date of
3 the enactment of the National Breast and Cer-
4 vical Cancer Early Detection Program Reau-
5 thorization of 2007, and annually thereafter,”
6 and inserting “2 years after the date of enact-
7 ment of the Bipartisan Health Care Act, and
8 every 5 years thereafter,”;

9 (B) by striking “Labor and Human Re-
10 sources” and inserting “Health, Education,
11 Labor, and Pensions”; and

12 (C) by striking “preceding fiscal year” and
13 inserting “preceding 2 fiscal years in the case
14 of the first report after the date of enactment
15 of the Bipartisan Health Care Act and pre-
16 ceding 5 fiscal years for each report there-
17 after”; and

18 (4) in section 1510(a) (42 U.S.C. 300n-5(a))—

19 (A) by striking “2011, and” and inserting
20 “2011,”; and

21 (B) by inserting “, and \$235,500,000 for
22 each of fiscal years 2025 through 2029” before
23 the period at the end before the period at the
24 end.

1 (b) GAO STUDY.—Not later than September 30,
2 2027, the Comptroller General of the United States shall
3 report to the Committee on Health, Education, Labor, and
4 Pensions of the Senate and the Committee on Energy and
5 Commerce of the House of Representatives on the work
6 of the National Breast and Cervical Cancer Early Detec-
7 tion Program, including—

8 (1) an estimate of the number of individuals eli-
9 gible for services provided under such program;

10 (2) a summary of trends in the number of indi-
11 viduals served through such program; and

12 (3) an assessment of any factors that may be
13 driving the trends identified under paragraph (2),
14 including any barriers to accessing breast and cer-
15 vical cancer screenings provided by such program.

16 **SEC. 709. DEONDRA DIXON INCLUDE PROJECT.**

17 Part B of title IV of the Public Health Service Act
18 (42 U.S.C. 284 et seq.) is amended by adding at the end
19 the following:

20 **“SEC. 409K. DOWN SYNDROME RESEARCH.**

21 “(a) IN GENERAL.—The Director of NIH shall carry
22 out a program of research, training, and investigation re-
23 lated to Down syndrome to be known as the ‘INvestigation
24 of Co-occurring conditions across the Lifespan to Under-

1 stand Down syndromE Project’ or the ‘INCLUDE
2 Project’.

3 “(b) PROGRAM ELEMENTS.—The program under
4 subsection (a) shall include—

5 “(1) high-risk, high reward research on the ef-
6 fects of trisomy 21 on human development and
7 health;

8 “(2) promoting research for participants with
9 Down syndrome across the lifespan, including cohort
10 studies to facilitate improved understanding of
11 Down syndrome and co-occurring conditions and de-
12 velopment of new interventions;

13 “(3) expanding the number of clinical trials
14 that are inclusive of, or expressly for, participants
15 with Down syndrome, including novel biomedical and
16 pharmacological interventions and other therapies
17 designed to promote or enhance activities of daily
18 living;

19 “(4) research on the biological mechanisms in
20 individuals with Down syndrome pertaining to struc-
21 tural, functional, and behavioral anomalies and dys-
22 function as well as stunted growth;

23 “(5) supporting research to improve diagnosis
24 and treatment of conditions co-occurring with Down
25 syndrome, including the identification of biomarkers

1 related to risk factors, diagnosis, and clinical re-
2 search and therapeutics;

3 “(6) research on the causes of increased preva-
4 lence, and concurrent treatment, of co-occurring con-
5 ditions, such as Alzheimer’s disease and related de-
6 mentias and autoimmunity, in individuals with Down
7 syndrome; and

8 “(7) research, training, and investigation on im-
9 proving the quality of life of individuals with Down
10 syndrome and their families.

11 “(c) COORDINATION; PRIORITIZING NONDUPLICA-
12 TIVE RESEARCH.—The Director of NIH shall ensure
13 that—

14 “(1) the programs and activities of the insti-
15 tutes and centers of the National Institutes of
16 Health relating to Down syndrome and co-occurring
17 conditions are coordinated, including through the
18 Office of the Director of NIH and priority-setting
19 reviews conducted pursuant to section 402(b)(3);
20 and

21 “(2) such institutes and centers, prioritize, as
22 appropriate, Down syndrome research that does not
23 duplicate existing research activities of the National
24 Institutes of Health.

1 “(d) CONSULTATION WITH STAKEHOLDERS.—In
2 carrying out activities under this section, the Director of
3 NIH shall, as appropriate and to the maximum extent fea-
4 sible, consult with relevant stakeholders, including patient
5 advocates, to ensure that such activities take into consid-
6 eration the needs of individuals with Down syndrome.

7 “(e) BIENNIAL REPORTS TO CONGRESS.—

8 “(1) IN GENERAL.—The Director of NIH shall
9 submit, on a biennial basis, to the Committee on
10 Energy and Commerce and the Subcommittee on
11 Labor, Health and Human Services, Education, and
12 Related Agencies of the Committee on Appropria-
13 tions of the House of Representatives and the Com-
14 mittee on Health, Education, Labor, and Pensions
15 and the Subcommittee on Labor, Health and
16 Human Services, Education, and Related Agencies
17 of the Committee on Appropriations of the Senate,
18 a report that catalogs the research conducted or
19 supported under this section.

20 “(2) CONTENTS.—Each report under para-
21 graph (1) shall include—

22 “(A) identification of the institute or cen-
23 ter involved;

24 “(B) a statement of whether the research
25 is or was being carried out directly by such in-

1 stitute or center or by multiple institutes and
2 centers; and

3 “(C) identification of any resulting real-
4 world evidence that is or may be used for clin-
5 ical research and medical care for patients with
6 Down syndrome.”.

7 **SEC. 710. IMPROVE INITIATIVE.**

8 Part B of title IV of the Public Health Service Act
9 (42 U.S.C. 284 et seq.), as amended by section 710, is
10 further amended by adding at the end the following:

11 **“SEC. 409L. IMPROVE INITIATIVE.**

12 “(a) IN GENERAL.—The Director of the National In-
13 stitutes of Health shall carry out a program of research
14 to improve health outcomes to be known as the Imple-
15 menting a Maternal health and PRegnancy Outcomes Vi-
16 sion for Everyone Initiative (referred to in this section as
17 the ‘Initiative’).

18 “(b) OBJECTIVES.—The Initiative shall—

19 “(1) advance research to—

20 “(A) reduce preventable causes of maternal
21 mortality and severe maternal morbidity;

22 “(B) reduce health disparities related to
23 maternal health outcomes, including such dis-
24 parities associated with medically underserved
25 populations; and

1 “(C) improve health for pregnant and
2 postpartum women before, during, and after
3 pregnancy;

4 “(2) use an integrated approach to understand
5 the factors, including biological, behavioral, and
6 other factors, that affect maternal mortality and se-
7 vere maternal morbidity by building an evidence
8 base for improved outcomes in specific regions of the
9 United States; and

10 “(3) target health disparities associated with
11 maternal mortality and severe maternal morbidity
12 by—

13 “(A) implementing and evaluating commu-
14 nity-based interventions for disproportionately
15 affected women; and

16 “(B) identifying risk factors and the un-
17 derlying biological mechanisms associated with
18 leading causes of maternal mortality and severe
19 maternal morbidity in the United States.

20 “(c) SUNSET.—The authority under this section shall
21 expire on September 30, 2029.”.

22 **SEC. 711. ORGAN PROCUREMENT AND TRANSPLANTATION**
23 **NETWORK.**

24 Section 372 of the Public Health Service Act (42
25 U.S.C. 274) is amended—

1 (1) in subsection (b)(2)—

2 (A) by moving the margins of subpara-
3 graphs (M) through (O) 2 ems to the left;

4 (B) in subparagraph (A)—

5 (i) in clause (i), by striking “, and”
6 and inserting “; and”; and

7 (ii) in clause (ii), by striking the
8 comma at the end and inserting a semi-
9 colon;

10 (C) in subparagraph (C), by striking
11 “twenty-four-hour telephone service” and in-
12 serting “24-hour telephone or information tech-
13 nology service”;

14 (D) in each of subparagraphs (B) through
15 (M), by striking the comma at the end and in-
16 serting a semicolon;

17 (E) in subparagraph (N), by striking
18 “transportation, and” and inserting “transpor-
19 tation;”;

20 (F) in subparagraph (O), by striking the
21 period and inserting a semicolon; and

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

23 “(P) encourage the integration of electronic
24 health records systems through application program-
25 ming interfaces (or successor technologies) among

1 hospitals, organ procurement organizations, and
2 transplant centers, including the use of automated
3 electronic hospital referrals and the grant of remote,
4 electronic access to hospital electronic health records
5 of potential donors by organ procurement organiza-
6 tions, in a manner that complies with the privacy
7 regulations promulgated under the Health Insurance
8 Portability and Accountability Act of 1996, at part
9 160 of title 45, Code of Federal Regulations, and
10 subparts A, C, and E of part 164 of such title (or
11 any successor regulations); and

12 “(Q) consider establishing a dashboard to dis-
13 play the number of transplants performed, the types
14 of transplants performed, the number and types of
15 organs that entered the Organ Procurement and
16 Transplantation Network system and failed to be
17 transplanted, and other appropriate statistics, which
18 should be updated more frequently than annually.”;
19 and

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

21 “(d) REGISTRATION FEES.—

22 “(1) IN GENERAL.—The Secretary may collect
23 registration fees from any member of the Organ
24 Procurement and Transplantation Network for each
25 transplant candidate such member places on the list

1 described in subsection (b)(2)(A)(i). Such registra-
 2 tion fees shall be collected and distributed only to
 3 support the operation of the Organ Procurement
 4 and Transplantation Network. Such registration fees
 5 are authorized to remain available until expended.

6 “(2) COLLECTION.—The Secretary may collect
 7 the registration fees under paragraph (1) directly or
 8 through awards made under subsection (b)(1)(A).

9 “(3) DISTRIBUTION.—Any amounts collected
 10 under this subsection shall—

11 “(A) be credited to the currently applicable
 12 appropriation, account, or fund of the Depart-
 13 ment of Health and Human Services as discre-
 14 tionary offsetting collections; and

15 “(B) be available, only to the extent and in
 16 the amounts provided in advance in appropria-
 17 tions Acts, to distribute such fees among
 18 awardees described in subsection (b)(1)(A).

19 “(4) TRANSPARENCY.—The Secretary shall—

20 “(A) promptly post on the website of the
 21 Organ Procurement and Transplantation Net-
 22 work—

23 “(i) the amount of registration fees
 24 collected under this subsection from each

1 member of the Organ Procurement and
2 Transplantation Network; and

3 “(ii) a list of activities such fees are
4 used to support; and

5 “(B) update the information posted pursu-
6 ant to subparagraph (A), as applicable for each
7 calendar quarter for which fees are collected
8 under paragraph (1).

9 “(5) GAO REVIEW.—Not later than 2 years
10 after the date of enactment of this subsection, the
11 Comptroller General of the United States shall, to
12 the extent data are available—

13 “(A) conduct a review concerning the ac-
14 tivities under this subsection; and

15 “(B) submit to the Committee on Health,
16 Education, Labor, and Pensions and the Com-
17 mittee on Finance of the Senate and the Com-
18 mittee on Energy and Commerce of the House
19 of Representatives, a report on such review, in-
20 cluding related recommendations, as applicable.

21 “(6) SUNSET.—The authority to collect reg-
22 istration fees under paragraph (1) shall expire on
23 the date that is 3 years after the date of enactment
24 of the Bipartisan Health Care Act.”.

1 **SEC. 712. HONOR OUR LIVING DONORS.**

2 (a) NO CONSIDERATION OF INCOME OF ORGAN RE-
3 CIPIENT.—Section 377 of the Public Health Service Act
4 (42 U.S.C. 274f) is amended—

5 (1) by redesignating subsections (c) through (f)
6 as subsections (d) through (g), respectively;

7 (2) by inserting after subsection (b) the fol-
8 lowing:

9 “(c) NO CONSIDERATION OF INCOME OF ORGAN RE-
10 CIPIENT.—The recipient of a grant under this section, in
11 providing reimbursement to a donating individual through
12 such grant, shall not give any consideration to the income
13 of the organ recipient.”; and

14 (3) in subsection (f), as so redesignated—

15 (A) in paragraph (1), by striking “sub-
16 section (c)(1)” and inserting “subsection
17 (d)(1)”; and

18 (B) in paragraph (2), by striking “sub-
19 section (c)(2)” and inserting “subsection
20 (d)(2)”.

21 (b) REMOVAL OF EXPECTATION OF PAYMENTS BY
22 ORGAN RECIPIENTS.—Section 377(e) of the Public
23 Health Service Act (42 U.S.C. 274f(e)), as redesignated
24 by subsection (a)(1), is amended—

25 (1) in paragraph (1), by adding “or” at the
26 end;

1 (2) in paragraph (2), by striking “; or” and in-
2 serting a period; and

3 (3) by striking paragraph (3).

4 (c) ANNUAL REPORT.—Section 377 of the Public
5 Health Service Act (42 U.S.C. 274f), as amended by sub-
6 sections (a) and (b), is amended by adding at the end the
7 following:

8 “(h) ANNUAL REPORT.—Not later than December 31
9 of each year, beginning in fiscal year 2026, the Secretary
10 shall—

11 “(1) prepare, submit to the Congress, and make
12 public a report on whether grants under this section
13 provided adequate funding during the preceding fis-
14 cal year to reimburse all donating individuals par-
15 ticipating in the grant program under this section
16 for all qualifying expenses; and

17 “(2) include in each such report—

18 “(A) the estimated number of all donating
19 individuals participating in the grant program
20 under this section who did not receive reim-
21 bursement for all qualifying expenses during
22 the preceding fiscal year; and

23 “(B) the total amount of funding that is
24 estimated to be necessary to fully reimburse all
25 donating individuals participating in the grant

1 program under this section for all qualifying ex-
 2 penses.”.

3 **SEC. 713. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

4 Section 409I(d)(1) of the Public Health Service Act
 5 (42 U.S.C. 284m(d)(1)) is amended by striking “section,”
 6 and all that follows through the period at the end and
 7 inserting “section, \$25,000,000 for each of fiscal years
 8 2025 through 2027.”.

9 **TITLE VIII—FOOD AND DRUG**
 10 **ADMINISTRATION**

11 **Subtitle A—Give Kids a Chance**

12 **SEC. 801. RESEARCH INTO PEDIATRIC USES OF DRUGS; AD-**
 13 **DITIONAL AUTHORITIES OF FOOD AND DRUG**
 14 **ADMINISTRATION REGARDING MOLECU-**
 15 **LARLY TARGETED CANCER DRUGS.**

16 (a) IN GENERAL.—

17 (1) ADDITIONAL ACTIVE INGREDIENT FOR AP-
 18 PLICATION DRUG; LIMITATION REGARDING NOVEL-
 19 COMBINATION APPLICATION DRUG.—Section
 20 505B(a)(3) of the Federal Food, Drug, and Cos-
 21 metic Act (21 U.S.C. 355c(a)(3)) is amended—

22 (A) by redesignating subparagraphs (B)
 23 and (C) as subparagraphs (C) and (D), respec-
 24 tively; and

1 (B) by striking subparagraph (A) and in-
2 serting the following:

3 “(A) IN GENERAL.—For purposes of para-
4 graph (1)(B), the investigation described in this
5 paragraph is a molecularly targeted pediatric
6 cancer investigation of—

7 “(i) the drug or biological product for
8 which the application referred to in such
9 paragraph is submitted; or

10 “(ii) such drug or biological product
11 used in combination with—

12 “(I) an active ingredient of a
13 drug or biological product—

14 “(aa) for which an approved
15 application under section 505(j)
16 under this Act or under section
17 351(k) of the Public Health
18 Service Act is in effect; and

19 “(bb) that is determined by
20 the Secretary, after consultation
21 with the applicant, to be part of
22 the standard of care for treating
23 a pediatric cancer; or

24 “(II) an active ingredient of a
25 drug or biological product—

1 “(aa) for which an approved
2 application under section 505(b)
3 of this Act or section 351(a) of
4 the Public Health Service Act to
5 treat an adult cancer is in effect
6 and is held by the same person
7 submitting the application under
8 paragraph (1)(B); and

9 “(bb) that is directed at a
10 molecular target that the Sec-
11 retary determines to be substan-
12 tially relevant to the growth or
13 progression of a pediatric cancer.

14 “(B) ADDITIONAL REQUIREMENTS.—

15 “(i) DESIGN OF INVESTIGATION.—A
16 molecularly targeted pediatric cancer inves-
17 tigation referred to in subparagraph (A)
18 shall be designed to yield clinically mean-
19 ingful pediatric study data that is gathered
20 using appropriate formulations for each
21 age group for which the study is required,
22 regarding dosing, safety, and preliminary
23 efficacy to inform potential pediatric label-
24 ing.

1 “(ii) LIMITATION.—An investigation
2 described in subparagraph (A)(ii) may be
3 required only if the drug or biological
4 product for which the application referred
5 to in paragraph (1)(B) contains either—

6 “(I) a single new active ingre-
7 dient; or

8 “(II) more than one active ingre-
9 dient, if an application for the com-
10 bination of active ingredients has not
11 previously been approved but each ac-
12 tive ingredient is in a drug product
13 that has been previously approved to
14 treat an adult cancer.

15 “(iii) RESULTS OF ALREADY-COM-
16 PLETED PRECLINICAL STUDIES OF APPLI-
17 CATION DRUG.—With respect to an inves-
18 tigation required pursuant to paragraph
19 (1)(B), the Secretary may require the re-
20 sults of any completed preclinical studies
21 relevant to the initial pediatric study plan
22 be submitted to the Secretary at the same
23 time that the initial pediatric study plan
24 required under subsection (e)(1) is sub-
25 mitted.

1 “(iv) RULE OF CONSTRUCTION RE-
2 GARDING INACTIVE INGREDIENTS.—With
3 respect to a combination of active ingredi-
4 ents referred to in subparagraph (A)(ii),
5 such subparagraph shall not be construed
6 as addressing the use of inactive ingredi-
7 ents with such combination.”.

8 (2) DETERMINATION OF APPLICABLE REQUIRE-
9 MENTS.—Section 505B(e)(1) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 355c(e)(1)) is
11 amended by adding at the end the following: “The
12 Secretary shall determine whether subparagraph (A)
13 or (B) of subsection (a)(1) applies with respect to an
14 application before the date on which the applicant is
15 required to submit the initial pediatric study plan
16 under paragraph (2)(A).”.

17 (3) CLARIFYING APPLICABILITY.—Section
18 505B(a)(1) of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 355c(a)(1)) is amended by
20 adding at the end the following:

21 “(C) RULE OF CONSTRUCTION.—No appli-
22 cation that is subject to the requirements of
23 subparagraph (B) shall be subject to the re-
24 quirements of subparagraph (A), and no appli-
25 cation (or supplement to an application) that is

1 subject to the requirements of subparagraph
2 (A) shall be subject to the requirements of sub-
3 paragraph (B).”.

4 (4) CONFORMING AMENDMENTS.—Section
5 505B(a) of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 355c(a)) is amended—

7 (A) in paragraph (3)(C), as redesignated
8 by paragraph (1)(A) of this subsection, by
9 striking “investigations described in this para-
10 graph” and inserting “investigations referred to
11 in subparagraph (A)”; and

12 (B) in paragraph (3)(D), as redesignated
13 by paragraph (1)(A) of this subsection, by
14 striking “the assessments under paragraph
15 (2)(B)” and inserting “the assessments re-
16 quired under paragraph (1)(A)”.

17 (b) GUIDANCE.—The Secretary of Health and
18 Human Services, acting through the Commissioner of
19 Food and Drugs, shall—

20 (1) not later than 12 months after the date of
21 enactment of this Act, issue draft guidance on the
22 implementation of the amendments made by sub-
23 section (a); and

1 (2) not later than 12 months after closing the
2 comment period on such draft guidance, finalize
3 such guidance.

4 (c) APPLICABILITY.—The amendments made by this
5 section apply with respect to any application under section
6 505(b) of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 355(b)) and any application under section 351(a)
8 of the Public Health Service Act (42 U.S.C. 262(a)), that
9 is submitted on or after the date that is 3 years after the
10 date of enactment of this Act.

11 (d) REPORTS TO CONGRESS.—

12 (1) SECRETARY OF HEALTH AND HUMAN SERV-
13 ICES.—Not later than 6 years after the date of en-
14 actment of this Act, the Secretary of Health and
15 Human Services shall submit to the Committee on
16 Energy and Commerce of the House of Representa-
17 tives and the Committee on Health, Education,
18 Labor, and Pensions of the Senate a report on the
19 Secretary's efforts, in coordination with industry, to
20 ensure implementation of the amendments made by
21 subsection (a).

22 (2) GAO STUDY AND REPORT.—

23 (A) STUDY.—Not later than 8 years after
24 the date of enactment of this Act, the Comp-
25 troller General of the United States shall con-

duct a study of the effectiveness of requiring assessments and investigations described in section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.355c), as amended by subsection (a), in the development of drugs and biological products for pediatric cancer indications, including consideration of any benefits to, or burdens on, pediatric cancer drug development.

(B) FINDINGS.—Not later than 10 years after the date of enactment of this Act, the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing the findings of the study conducted under subparagraph (A).

SEC. 802. ENSURING COMPLETION OF PEDIATRIC STUDY REQUIREMENTS.

(a) EQUAL ACCOUNTABILITY FOR PEDIATRIC STUDY REQUIREMENTS.—Section 505B(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)) is amended—

1 (1) in paragraph (1), by striking “Beginning
2 270” and inserting “NONCOMPLIANCE LETTER.—
3 Beginning 270”;

4 (2) in paragraph (2)—

5 (A) by striking “The drug or” and insert-
6 ing “EFFECT OF NONCOMPLIANCE.—The drug
7 or”; and

8 (B) by striking “(except that the drug or
9 biological product shall not be subject to action
10 under section 303)” and inserting “(except that
11 the drug or biological product shall be subject
12 to action under section 303 only if such person
13 demonstrated a lack of due diligence in satis-
14 fying the applicable requirement)”; and

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

16 “(3) LIMITATION.—The Secretary shall not
17 issue enforcement actions under section 303 for fail-
18 ures under this subsection in the case of a drug or
19 biological product that is no longer marketed.”.

20 (b) DUE DILIGENCE.—Section 505B(d) of the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)),
22 as amended by subsection (a), is further amended by add-
23 ing at the end the following:

24 “(4) DUE DILIGENCE.—Before the Secretary
25 may conclude that a person failed to submit or oth-

1 erwise meet a requirement as described in the mat-
 2 ter preceding paragraph (1), the Secretary shall—

3 “(A) issue a noncompliance letter pursuant
 4 to paragraph (1);

5 “(B) provide such person with a 45-day
 6 period beginning on the date of receipt of such
 7 noncompliance letter to respond in writing as
 8 set forth in such paragraph; and

9 “(C) after reviewing such written response,
 10 determine whether the person demonstrated a
 11 lack of due diligence in satisfying such require-
 12 ment.”.

13 (c) CONFORMING AMENDMENTS.—Section
 14 303(f)(4)(A) of the Federal Food, Drug, and Cosmetic Act
 15 (21 U.S.C. 333(f)(4)(A)) is amended by striking “or 505–
 16 1” and inserting “505–1, or 505B”.

17 (d) TRANSITION RULE.—The Secretary of Health
 18 and Human Services may take enforcement action under
 19 section 303 of the Federal Food, Drug, and Cosmetic Act
 20 (21 U.S.C. 333) only for failures described in section
 21 505B(d) of such Act (21 U.S.C. 355c(d)) that occur on
 22 or after the date that is 180 days after the date of enact-
 23 ment of this Act.

1 **SEC. 803. FDA REPORT ON PREA ENFORCEMENT.**

2 Section 508(b) of the Food and Drug Administration
3 Safety and Innovation Act (21 U.S.C. 355c–1(b)) is
4 amended—

5 (1) in paragraph (11), by striking the semicolon
6 at the end and inserting “, including an evaluation
7 of compliance with deadlines provided for in defer-
8 rals and deferral extensions;”;

9 (2) in paragraph (15), by striking “and” at the
10 end;

11 (3) in paragraph (16), by striking the period at
12 the end and inserting “; and”; and

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

14 “(17) a listing of penalties, settlements, or pay-
15 ments under section 303 of the Federal Food, Drug,
16 and Cosmetic Act (21 U.S.C. 353) for failure to
17 comply with requirements under such section 505B,
18 including, for each penalty, settlement, or payment,
19 the name of the drug, the sponsor thereof, and the
20 amount of the penalty, settlement, or payment im-
21 posed; and”.

22 **SEC. 804. EXTENSION OF AUTHORITY TO ISSUE PRIORITY**
23 **REVIEW VOUCHERS TO ENCOURAGE TREAT-**
24 **MENTS FOR RARE PEDIATRIC DISEASES.**

25 (a) EXTENSION.—Paragraph (5) of section 529(b) of
26 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 360ff(b)) is amended by striking “December 20, 2024, un-
 2 less” and all that follows through the period at the end
 3 and inserting “September 30, 2029.”.

4 (b) USER FEE PAYMENT.—Section 529(c)(4) of the
 5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 6 360ff(c)(4)) is amended by striking subparagraph (A) and
 7 inserting the following:

8 “(A) IN GENERAL.—The priority review
 9 user fee required by this subsection shall be due
 10 upon the submission of a human drug applica-
 11 tion under section 505(b)(1) or section 351(a)
 12 of the Public Health Service Act for which the
 13 priority review voucher is used. All other user
 14 fees associated with the human drug application
 15 shall be due as required by the Secretary or
 16 under applicable law.”.

17 (c) GAO REPORT ON EFFECTIVENESS OF RARE PE-
 18 DIATRIC DISEASE PRIORITY VOUCHER AWARDS IN
 19 INCENTIVIZING RARE PEDIATRIC DISEASE DRUG DEVEL-
 20 OPMENT.—

21 (1) GAO STUDY.—

22 (A) STUDY.—The Comptroller General of
 23 the United States shall conduct a study of the
 24 effectiveness of awarding rare pediatric disease
 25 priority vouchers under section 529 of the Fed-

1 eral Food, Drug, and Cosmetic Act (21 U.S.C.
2 360ff), as amended by subsection (a), in the de-
3 velopment of human drug products that treat or
4 prevent rare pediatric diseases (as defined in
5 such section 529).

6 (B) CONTENTS OF STUDY.—In conducting
7 the study under subparagraph (A), the Comp-
8 troller General shall examine the following:

9 (i) The indications for each drug or
10 biological product that—

11 (I) is the subject of a rare pedi-
12 atric disease product application (as
13 defined in section 529 of the Federal
14 Food, Drug, and Cosmetic Act (21
15 U.S.C. 360ff)) for which a priority re-
16 view voucher was awarded; and

17 (II) was approved under section
18 505 of the Federal Food, Drug, and
19 Cosmetic Act (42 U.S.C. 355) or li-
20 censed under section 351 of the Pub-
21 lic Health Service Act (42 U.S.C.
22 262).

23 (ii) Whether, and to what extent, an
24 unmet need related to the treatment or
25 prevention of a rare pediatric disease was

1 met through the approval or licensure of
2 such a drug or biological product.

3 (iii) The size of the company to which
4 a priority review voucher was awarded
5 under section 529 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 360ff)
7 for such a drug or biological product.

8 (iv) The value of such priority review
9 voucher if transferred.

10 (v) Identification of each drug for
11 which a priority review voucher awarded
12 under such section 529 was used.

13 (vi) The size of the company using
14 each priority review voucher awarded
15 under such section 529.

16 (vii) The length of the period of time
17 between the date on which a priority re-
18 view voucher was awarded under such sec-
19 tion 529 and the date on which it was
20 used.

21 (viii) Whether, and to what extent, an
22 unmet need related to the treatment or
23 prevention of a rare pediatric disease was
24 met through the approval under section
25 505 of the Federal Food, Drug, and Cos-

1 metic Act (42 U.S.C. 355) or licensure
2 under section 351 of the Public Health
3 Service Act (42 U.S.C. 262) of a drug for
4 which a priority review voucher was used.

5 (ix) Whether, and to what extent,
6 companies were motivated by the avail-
7 ability of priority review vouchers under
8 section 529 of the Federal Food, Drug,
9 and Cosmetic Act (21 U.S.C. 360ff) to at-
10 tempt to develop a drug for a rare pedi-
11 atric disease.

12 (x) Whether, and to what extent, pedi-
13 atric review vouchers awarded under such
14 section were successful in stimulating de-
15 velopment and expedited patient access to
16 drug products for treatment or prevention
17 of a rare pediatric disease that wouldn't
18 otherwise take place without the incentive
19 provided by such vouchers.

20 (xi) The impact of such priority re-
21 view vouchers on the workload, review
22 process, and public health prioritization ef-
23 forts of the Food and Drug Administra-
24 tion.

1 (xii) Any other incentives in Federal
2 law that exist for companies developing
3 drugs or biological products described in
4 clause (i).

5 (2) REPORT ON FINDINGS.—Not later than 5
6 years after the date of the enactment of this Act, the
7 Comptroller General of the United States shall sub-
8 mit to the Committee on Energy and Commerce of
9 the House of Representatives and the Committee on
10 Health, Education, Labor, and Pensions of the Sen-
11 ate a report containing the findings of the study
12 conducted under paragraph (1).

13 **SEC. 805. LIMITATIONS ON EXCLUSIVE APPROVAL OR LI-**
14 **CENSURE OF ORPHAN DRUGS.**

15 (a) IN GENERAL.—Section 527 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

17 (1) in subsection (a), in the matter following
18 paragraph (2), by striking “same disease or condi-
19 tion” and inserting “same approved use or indica-
20 tion within such rare disease or condition”;

21 (2) in subsection (b)—

22 (A) in the matter preceding paragraph (1),
23 by striking “same rare disease or condition”
24 and inserting “same approved use or indication

1 for which such 7-year period applies to such al-
2 ready approved or licensed drug”; and

3 (B) in paragraph (1), by inserting “, relat-
4 ing to the approved use or indication,” after
5 “the needs”;

6 (3) in subsection (c)(1), by striking “same rare
7 disease or condition as the already approved drug”
8 and inserting “same use or indication for which the
9 already approved or licensed drug was approved or
10 licensed”; and

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

12 “(f) APPROVED USE OR INDICATION DEFINED.—In
13 this section, the term ‘approved use or indication’ means
14 the use or indication approved under section 505 of this
15 Act or licensed under section 351 of the Public Health
16 Service Act for a drug designated under section 526 for
17 a rare disease or condition.”.

18 (b) APPLICATION OF AMENDMENTS.—The amend-
19 ments made by subsection (a) shall apply with respect to
20 any drug designated under section 526 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regard-
22 less of the date on which the drug was so designated, and
23 regardless of the date on which the drug was approved
24 under section 505 of such Act (21 U.S.C. 355) or licensed

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

3 **Subtitle B—United States-Abraham**
4 **Accords Cooperation and Security**

5 **SEC. 811. ESTABLISHMENT OF ABRAHAM ACCORDS OFFICE**
6 **WITHIN FOOD AND DRUG ADMINISTRATION.**

7 (a) IN GENERAL.—Chapter X of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-
9 ed by adding at the end the following:

10 **“SEC. 1015. ABRAHAM ACCORDS OFFICE.**

11 “(a) IN GENERAL.—The Secretary, acting through
12 the Commissioner of Food and Drugs, shall establish with-
13 in the Food and Drug Administration an office, to be
14 known as the Abraham Accords Office, to be headed by
15 a director.

16 “(b) OFFICE.—Not later than 2 years after the date
17 of enactment of this section, the Secretary shall—

18 “(1) in consultation with the governments of
19 Abraham Accords countries, as well as appropriate
20 United States Government diplomatic and security
21 personnel—

22 “(A) select the location of the Abraham
23 Accords Office in an Abraham Accords country;
24 and

25 “(B) establish such office; and

1 “(2) assign to such office such personnel of the
2 Food and Drug Administration as the Secretary de-
3 termines necessary to carry out the functions of
4 such office.

5 “(c) DUTIES.—The Secretary, acting through the Di-
6 rector of the Abraham Accords Office, shall—

7 “(1) after the Abraham Accords Office is estab-
8 lished—

9 “(A) as part of the Food and Drug Admin-
10 istration’s work to strengthen the international
11 oversight of regulated commodities, provide
12 technical assistance to regulatory partners in
13 Abraham Accords countries on strengthening
14 regulatory oversight and converging regulatory
15 requirements for the oversight of regulated
16 products, including good manufacturing prac-
17 tices and other issues relevant to manufacturing
18 medical products that are regulated by the
19 Food and Drug Administration; and

20 “(B) facilitate interactions between the
21 Food and Drug Administration and interested
22 parties in Abraham Accords countries, including
23 by sharing relevant information regarding
24 United States regulatory pathways with such
25 parties, and facilitate feedback on the research,

1 development, and manufacturing of products
2 regulated in accordance with this Act; and

3 “(2) carry out other functions and activities as
4 the Secretary determines to be necessary to carry
5 out this section.

6 “(d) ABRAHAM ACCORDS COUNTRY DEFINED.—In
7 this section, the term ‘Abraham Accords country’ means
8 a country identified by the Department of State as having
9 signed the Abraham Accords Declaration.

10 “(e) NATIONAL SECURITY.—Nothing in this section
11 shall be construed to require any action inconsistent with
12 a national security recommendation provided by the Fed-
13 eral Government.”.

14 (b) REPORT TO CONGRESS.—

15 (1) IN GENERAL.—Not later than 3 years after
16 the date of enactment of this Act, the Secretary of
17 Health and Human Services shall submit to the
18 Congress a report on the Abraham Accords Office,
19 including—

20 (A) an evaluation of how the Office has ad-
21 vanced progress toward conformance with Food
22 and Drug Administration regulatory require-
23 ments by manufacturers in the Abraham Ac-
24 cords countries;

1 (B) a numerical count of parties that the
 2 Office has helped facilitate interactions or feed-
 3 back pursuant to section 1015(c)(1)(B) of the
 4 Federal Food, Drug, and Cosmetic Act (as
 5 added by subsection (a));

6 (C) a summary of technical assistance pro-
 7 vided to regulatory partners in Abraham Ac-
 8 cords countries pursuant to subparagraph (A)
 9 of such section 1015(c)(1); and

10 (D) recommendations for increasing and
 11 improving coordination between the Food and
 12 Drug Administration and entities in Abraham
 13 Accords countries.

14 (2) ABRAHAM ACCORDS COUNTRY DEFINED.—
 15 In this subsection, the term “Abraham Accords
 16 country” has the meaning given such term in section
 17 1015(d) of the Federal Food, Drug, and Cosmetic
 18 Act (as added by subsection (a)).

19 **TITLE IX—LOWERING**
 20 **PRESCRIPTION DRUG COSTS**

21 **SEC. 901. OVERSIGHT OF PHARMACY BENEFIT MANAGE-**
 22 **MENT SERVICES.**

23 (a) PUBLIC HEALTH SERVICE ACT.—Title XXVII of
 24 the Public Health Service Act (42 U.S.C. 300gg et seq.)
 25 is amended—

1 (1) in part D (42 U.S.C. 300gg–111 et seq.),
2 by adding at the end the following new section:

3 **“SEC. 2799A–11. OVERSIGHT OF ENTITIES THAT PROVIDE**
4 **PHARMACY BENEFIT MANAGEMENT SERV-**
5 **ICES.**

6 “(a) IN GENERAL.—For plan years beginning on or
7 after the date that is 30 months after the date of enact-
8 ment of this section (referred to in this subsection and
9 subsection (b) as the ‘effective date’), a group health plan
10 or a health insurance issuer offering group health insur-
11 ance coverage, or an entity providing pharmacy benefit
12 management services on behalf of such a plan or issuer,
13 shall not enter into a contract, including an extension or
14 renewal of a contract, entered into on or after the effective
15 date, with an applicable entity unless such applicable enti-
16 ty agrees to—

17 “(1) not limit or delay the disclosure of infor-
18 mation to the group health plan (including such a
19 plan offered through a health insurance issuer) in
20 such a manner that prevents an entity providing
21 pharmacy benefit management services on behalf of
22 a group health plan or health insurance issuer offer-
23 ing group health insurance coverage from making
24 the reports described in subsection (b); and

1 “(2) provide the entity providing pharmacy ben-
2 efit management services on behalf of a group health
3 plan or health insurance issuer relevant information
4 necessary to make the reports described in sub-
5 section (b).

6 “(b) REPORTS.—

7 “(1) IN GENERAL.—For plan years beginning
8 on or after the effective date, in the case of any con-
9 tract between a group health plan or a health insur-
10 ance issuer offering group health insurance coverage
11 offered in connection with such a plan and an entity
12 providing pharmacy benefit management services on
13 behalf of such plan or issuer, including an extension
14 or renewal of such a contract, entered into on or
15 after the effective date, the entity providing phar-
16 macy benefit management services on behalf of such
17 a group health plan or health insurance issuer, not
18 less frequently than every 6 months (or, at the re-
19 quest of a group health plan, not less frequently
20 than quarterly, and under the same conditions,
21 terms, and cost of the semiannual report under this
22 subsection), shall submit to the group health plan a
23 report in accordance with this section. Each such re-
24 port shall be made available to such group health
25 plan in plain language, in a machine-readable for-

1 mat, and as the Secretary may determine, other for-
2 mats. Each such report shall include the information
3 described in paragraph (2).

4 “(2) INFORMATION DESCRIBED.—For purposes
5 of paragraph (1), the information described in this
6 paragraph is, with respect to drugs covered by a
7 group health plan or group health insurance cov-
8 erage offered by a health insurance issuer in connec-
9 tion with a group health plan during each reporting
10 period—

11 “(A) in the case of a group health plan
12 that is offered by a specified large employer or
13 that is a specified large plan, and is not offered
14 as health insurance coverage, or in the case of
15 health insurance coverage for which the election
16 under paragraph (3) is made for the applicable
17 reporting period—

18 “(i) a list of drugs for which a claim
19 was filed and, with respect to each such
20 drug on such list—

21 “(I) the contracted compensation
22 paid by the group health plan or
23 health insurance issuer for each cov-
24 ered drug (identified by the National
25 Drug Code) to the entity providing

1 pharmacy benefit management serv-
2 ices or other applicable entity on be-
3 half of the group health plan or health
4 insurance issuer;

5 “(II) the contracted compensa-
6 tion paid to the pharmacy, by any en-
7 tity providing pharmacy benefit man-
8 agement services or other applicable
9 entity on behalf of the group health
10 plan or health insurance issuer, for
11 each covered drug (identified by the
12 National Drug Code);

13 “(III) for each such claim, the
14 difference between the amount paid
15 under subclause (I) and the amount
16 paid under subclause (II);

17 “(IV) the proprietary name, es-
18 tablished name or proper name, and
19 the National Drug Code;

20 “(V) for each claim for the drug
21 (including original prescriptions and
22 refills) and for each dosage unit of the
23 drug for which a claim was filed, the
24 type of dispensing channel used to

1 furnish the drug, including retail, mail
2 order, or specialty pharmacy;

3 “(VI) with respect to each drug
4 dispensed, for each type of dispensing
5 channel (including retail, mail order,
6 or specialty pharmacy)—

7 “(aa) whether such drug is a
8 brand name drug or a generic
9 drug, and—

10 “(AA) in the case of a
11 brand name drug, the whole-
12 sale acquisition cost, listed
13 as cost per days supply and
14 cost per dosage unit, on the
15 date such drug was dis-
16 pensed; and

17 “(BB) in the case of a
18 generic drug, the average
19 wholesale price, listed as
20 cost per days supply and
21 cost per dosage unit, on the
22 date such drug was dis-
23 pensed; and

24 “(bb) the total number of—

1 “(AA) prescription
2 claims (including original
3 prescriptions and refills);

4 “(BB) participants and
5 beneficiaries for whom a
6 claim for such drug was
7 filed through the applicable
8 dispensing channel;

9 “(CC) dosage units and
10 dosage units per fill of such
11 drug; and

12 “(DD) days supply of
13 such drug per fill;

14 “(VII) the net price per course of
15 treatment or single fill, such as a 30-
16 day supply or 90-day supply to the
17 plan or coverage after rebates, fees,
18 alternative discounts, or other remun-
19 eration received from applicable enti-
20 ties;

21 “(VIII) the total amount of out-
22 of-pocket spending by participants
23 and beneficiaries on such drug, in-
24 cluding spending through copayments,
25 coinsurance, and deductibles, but not

1 including any amounts spent by par-
2 ticipants and beneficiaries on drugs
3 not covered under the plan or cov-
4 erage, or for which no claim is sub-
5 mitted under the plan or coverage;

6 “(IX) the total net spending on
7 the drug;

8 “(X) the total amount received,
9 or expected to be received, by the plan
10 or issuer from any applicable entity in
11 rebates, fees, alternative discounts, or
12 other remuneration;

13 “(XI) the total amount received,
14 or expected to be received, by the enti-
15 ty providing pharmacy benefit man-
16 agement services, from applicable en-
17 tities, in rebates, fees, alternative dis-
18 counts, or other remuneration from
19 such entities—

20 “(aa) for claims incurred
21 during the reporting period; and

22 “(bb) that is related to utili-
23 zation of such drug or spending
24 on such drug; and

1 “(XII) to the extent feasible, in-
2 formation on the total amount of re-
3 muneration for such drug, including
4 copayment assistance dollars paid, co-
5 payment cards applied, or other dis-
6 counts provided by each drug manu-
7 facturer (or entity administering co-
8 payment assistance on behalf of such
9 drug manufacturer), to the partici-
10 pants and beneficiaries enrolled in
11 such plan or coverage;

12 “(ii) a list of each therapeutic class
13 (as defined by the Secretary) for which a
14 claim was filed under the group health
15 plan or health insurance coverage during
16 the reporting period, and, with respect to
17 each such therapeutic class—

18 “(I) the total gross spending on
19 drugs in such class before rebates,
20 price concessions, alternative dis-
21 counts, or other remuneration from
22 applicable entities;

23 “(II) the net spending in such
24 class after such rebates, price conces-

1 sions, alternative discounts, or other
2 remuneration from applicable entities;

3 “(III) the total amount received,
4 or expected to be received, by the enti-
5 ty providing pharmacy benefit man-
6 agement services, from applicable en-
7 tities, in rebates, fees, alternative dis-
8 counts, or other remuneration from
9 such entities—

10 “(aa) for claims incurred
11 during the reporting period; and

12 “(bb) that is related to utili-
13 zation of drugs or drug spending;

14 “(IV) the average net spending
15 per 30-day supply and per 90-day
16 supply by the plan or by the issuer
17 with respect to such coverage and its
18 participants and beneficiaries, among
19 all drugs within the therapeutic class
20 for which a claim was filed during the
21 reporting period;

22 “(V) the number of participants
23 and beneficiaries who filled a prescrip-
24 tion for a drug in such class, includ-

1 ing the National Drug Code for each
2 such drug;

3 “(VI) if applicable, a description
4 of the formulary tiers and utilization
5 mechanisms (such as prior authoriza-
6 tion or step therapy) employed for
7 drugs in that class; and

8 “(VII) the total out-of-pocket
9 spending under the plan or coverage
10 by participants and beneficiaries, in-
11 cluding spending through copayments,
12 coinsurance, and deductibles, but not
13 including any amounts spent by par-
14 ticipants and beneficiaries on drugs
15 not covered under the plan or cov-
16 erage or for which no claim is sub-
17 mitted under the plan or coverage;

18 “(iii) with respect to any drug for
19 which gross spending under the group
20 health plan or health insurance coverage
21 exceeded \$10,000 during the reporting pe-
22 riod or, in the case that gross spending
23 under the group health plan or coverage
24 exceeded \$10,000 during the reporting pe-
25 riod with respect to fewer than 50 drugs,

1 with respect to the 50 prescription drugs
2 with the highest spending during the re-
3 porting period—

4 “(I) a list of all other drugs in
5 the same therapeutic class as such
6 drug;

7 “(II) if applicable, the rationale
8 for the formulary placement of such
9 drug in that therapeutic category or
10 class, selected from a list of standard
11 rationales established by the Sec-
12 retary, in consultation with stake-
13 holders; and

14 “(III) any change in formulary
15 placement compared to the prior plan
16 year; and

17 “(iv) in the case that such plan or
18 issuer (or an entity providing pharmacy
19 benefit management services on behalf of
20 such plan or issuer) has an affiliated phar-
21 macy or pharmacy under common owner-
22 ship, including mandatory mail and spe-
23 cialty home delivery programs, retail and
24 mail auto-refill programs, and cost sharing

1 assistance incentives funded by an entity
2 providing pharmacy benefit services—

3 “(I) an explanation of any ben-
4 efit design parameters that encourage
5 or require participants and bene-
6 ficiaries in the plan or coverage to fill
7 prescriptions at mail order, specialty,
8 or retail pharmacies;

9 “(II) the percentage of total pre-
10 scriptions dispensed by such phar-
11 macies to participants or beneficiaries
12 in such plan or coverage; and

13 “(III) a list of all drugs dis-
14 pensed by such pharmacies to partici-
15 pants or beneficiaries enrolled in such
16 plan or coverage, and, with respect to
17 each drug dispensed—

18 “(aa) the amount charged,
19 per dosage unit, per 30-day sup-
20 ply, or per 90-day supply (as ap-
21 plicable) to the plan or issuer,
22 and to participants and bene-
23 ficiaries;

24 “(bb) the median amount
25 charged to such plan or issuer,

1 and the interquartile range of the
2 costs, per dosage unit, per 30-
3 day supply, and per 90-day sup-
4 ply, including amounts paid by
5 the participants and bene-
6 ficiaries, when the same drug is
7 dispensed by other pharmacies
8 that are not affiliated with or
9 under common ownership with
10 the entity and that are included
11 in the pharmacy network of such
12 plan or coverage;

13 “(cc) the lowest cost per
14 dosage unit, per 30-day supply
15 and per 90-day supply, for each
16 such drug, including amounts
17 charged to the plan or coverage
18 and to participants and bene-
19 ficiaries, that is available from
20 any pharmacy included in the
21 network of such plan or coverage;
22 and

23 “(dd) the net acquisition
24 cost per dosage unit, per 30-day
25 supply, and per 90-day supply, if

1 such drug is subject to a max-
2 imum price discount; and

3 “(B) with respect to any group health
4 plan, including group health insurance coverage
5 offered in connection with such a plan, regard-
6 less of whether the plan or coverage is offered
7 by a specified large employer or whether it is a
8 specified large plan—

9 “(i) a summary document for the
10 group health plan that includes such infor-
11 mation described in clauses (i) through (iv)
12 of subparagraph (A), as specified by the
13 Secretary through guidance, program in-
14 struction, or otherwise (with no require-
15 ment of notice and comment rulemaking),
16 that the Secretary determines useful to
17 group health plans for purposes of select-
18 ing pharmacy benefit management serv-
19 ices, such as an estimated net price to
20 group health plan and participant or bene-
21 ficiary, a cost per claim, the fee structure
22 or reimbursement model, and estimated
23 cost per participant or beneficiary;

24 “(ii) a summary document for plans
25 and issuers to provide to participants and

1 beneficiaries, which shall be made available
2 to participants or beneficiaries upon re-
3 quest to their group health plan (including
4 in the case of group health insurance cov-
5 erage offered in connection with such a
6 plan), that—

7 “(I) contains such information
8 described in clauses (iii), (iv), (v), and
9 (vi), as applicable, as specified by the
10 Secretary through guidance, program
11 instruction, or otherwise (with no re-
12 quirement of notice and comment
13 rulemaking) that the Secretary deter-
14 mines useful to participants or bene-
15 ficiaries in better understanding the
16 plan or coverage or benefits under
17 such plan or coverage;

18 “(II) contains only aggregate in-
19 formation; and

20 “(III) states that participants
21 and beneficiaries may request specific,
22 claims-level information required to be
23 furnished under subsection (c) from
24 the group health plan or health insur-
25 ance issuer; and

1 “(iii) with respect to drugs covered by
2 such plan or coverage during such report-
3 ing period—

4 “(I) the total net spending by the
5 plan or coverage for all such drugs;

6 “(II) the total amount received,
7 or expected to be received, by the plan
8 or issuer from any applicable entity in
9 rebates, fees, alternative discounts, or
10 other remuneration; and

11 “(III) to the extent feasible, in-
12 formation on the total amount of re-
13 muneration for such drugs, including
14 copayment assistance dollars paid, co-
15 payment cards applied, or other dis-
16 counts provided by each drug manu-
17 facturer (or entity administering co-
18 payment assistance on behalf of such
19 drug manufacturer) to participants
20 and beneficiaries;

21 “(iv) amounts paid directly or indi-
22 rectly in rebates, fees, or any other type of
23 compensation (as defined in section
24 408(b)(2)(B)(ii)(dd)(AA) of the Employee
25 Retirement Income Security Act) to bro-

1 kerage firms, brokers, consultants, advi-
2 sors, or any other individual or firm, for—

3 “(I) the referral of the group
4 health plan’s or health insurance
5 issuer’s business to an entity pro-
6 viding pharmacy benefit management
7 services, including the identity of the
8 recipient of such amounts;

9 “(II) consideration of the entity
10 providing pharmacy benefit manage-
11 ment services by the group health
12 plan or health insurance issuer; or

13 “(III) the retention of the entity
14 by the group health plan or health in-
15 surance issuer;

16 “(v) an explanation of any benefit de-
17 sign parameters that encourage or require
18 participants and beneficiaries in such plan
19 or coverage to fill prescriptions at mail
20 order, specialty, or retail pharmacies that
21 are affiliated with or under common own-
22 ership with the entity providing pharmacy
23 benefit management services under such
24 plan or coverage, including mandatory mail
25 and specialty home delivery programs, re-

1 tail and mail auto-refill programs, and
 2 cost-sharing assistance incentives directly
 3 or indirectly funded by such entity; and

4 “(vi) total gross spending on all drugs
 5 under the plan or coverage during the re-
 6 porting period.

7 “(3) OPT-IN FOR GROUP HEALTH INSURANCE
 8 COVERAGE OFFERED BY A SPECIFIED LARGE EM-
 9 PLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In
 10 the case of group health insurance coverage offered
 11 in connection with a group health plan that is of-
 12 fered by a specified large employer or is a specified
 13 large plan, such group health plan may, on an an-
 14 nual basis, for plan years beginning on or after the
 15 date that is 30 months after the date of enactment
 16 of this section, elect to require an entity providing
 17 pharmacy benefit management services on behalf of
 18 the health insurance issuer to submit to such group
 19 health plan a report that includes all of the informa-
 20 tion described in paragraph (2)(A), in addition to
 21 the information described in paragraph (2)(B).

22 “(4) PRIVACY REQUIREMENTS.—

23 “(A) IN GENERAL.—An entity providing
 24 pharmacy benefit management services on be-
 25 half of a group health plan or a health insur-

1 ance issuer offering group health insurance cov-
2 erage shall report information under paragraph
3 (1) in a manner consistent with the privacy reg-
4 ulations promulgated under section 13402(a) of
5 the Health Information Technology for Eco-
6 nomic and Clinical Health Act and consistent
7 with the privacy regulations promulgated under
8 the Health Insurance Portability and Account-
9 ability Act of 1996 in part 160 and subparts A
10 and E of part 164 of title 45, Code of Federal
11 Regulations (or successor regulations) (referred
12 to in this paragraph as the ‘HIPAA privacy
13 regulations’) and shall restrict the use and dis-
14 closure of such information according to such
15 privacy regulations and such HIPAA privacy
16 regulations.

17 “(B) ADDITIONAL REQUIREMENTS.—

18 “(i) IN GENERAL.—An entity pro-
19 viding pharmacy benefit management serv-
20 ices on behalf of a group health plan or
21 health insurance issuer offering group
22 health insurance coverage that submits a
23 report under paragraph (1) shall ensure
24 that such report contains only summary
25 health information, as defined in section

1 164.504(a) of title 45, Code of Federal
2 Regulations (or successor regulations).

3 “(ii) RESTRICTIONS.—In carrying out
4 this subsection, a group health plan shall
5 comply with section 164.504(f) of title 45,
6 Code of Federal Regulations (or a suc-
7 cessor regulation), and a plan sponsor shall
8 act in accordance with the terms of the
9 agreement described in such section.

10 “(C) RULE OF CONSTRUCTION.—

11 “(i) Nothing in this section shall be
12 construed to modify the requirements for
13 the creation, receipt, maintenance, or
14 transmission of protected health informa-
15 tion under the HIPAA privacy regulations.

16 “(ii) Nothing in this section shall be
17 construed to affect the application of any
18 Federal or State privacy or civil rights law,
19 including the HIPAA privacy regulations,
20 the Genetic Information Nondiscrimination
21 Act of 2008 (Public Law 110–233) (in-
22 cluding the amendments made by such
23 Act), the Americans with Disabilities Act
24 of 1990 (42 U.S.C. 12101 et seq.), section
25 504 of the Rehabilitation Act of 1973 (29

1 U.S.C. 794), section 1557 of the Patient
2 Protection and Affordable Care Act (42
3 U.S.C. 18116), title VI of the Civil Rights
4 Act of 1964 (42 U.S.C. 2000d), and title
5 VII of the Civil Rights Act of 1964 (42
6 U.S.C. 2000e).

7 “(D) WRITTEN NOTICE.—Each plan year,
8 group health plans, including with respect to
9 group health insurance coverage offered in con-
10 nection with a group health plan, shall provide
11 to each participant or beneficiary written notice
12 informing the participant or beneficiary of the
13 requirement for entities providing pharmacy
14 benefit management services on behalf of the
15 group health plan or health insurance issuer of-
16 fering group health insurance coverage to sub-
17 mit reports to group health plans under para-
18 graph (1), as applicable, which may include in-
19 corporating such notification in plan documents
20 provided to the participant or beneficiary, or
21 providing individual notification.

22 “(E) LIMITATION TO BUSINESS ASSOCI-
23 ATES.—A group health plan receiving a report
24 under paragraph (1) may disclose such informa-
25 tion only to the entity from which the report

1 was received or to that entity's business associ-
2 ates as defined in section 160.103 of title 45,
3 Code of Federal Regulations (or successor regu-
4 lations) or as permitted by the HIPAA privacy
5 regulations.

6 “(F) CLARIFICATION REGARDING PUBLIC
7 DISCLOSURE OF INFORMATION.—Nothing in
8 this section shall prevent an entity providing
9 pharmacy benefit management services on be-
10 half of a group health plan or health insurance
11 issuer offering group health insurance coverage,
12 from placing reasonable restrictions on the pub-
13 lic disclosure of the information contained in a
14 report described in paragraph (1), except that
15 such plan, issuer, or entity may not—

16 “(i) restrict disclosure of such report
17 to the Department of Health and Human
18 Services, the Department of Labor, or the
19 Department of the Treasury; or

20 “(ii) prevent disclosure for the pur-
21 poses of subsection (c), or any other public
22 disclosure requirement under this section.

23 “(G) LIMITED FORM OF REPORT.—The
24 Secretary shall define through rulemaking a
25 limited form of the report under paragraph (1)

1 required with respect to any group health plan
2 established by a plan sponsor that is, or is af-
3 filiated with, a drug manufacturer, drug whole-
4 saler, or other direct participant in the drug
5 supply chain, in order to prevent anti-competi-
6 tive behavior.

7 “(5) STANDARD FORMAT AND REGULATIONS.—

8 “(A) IN GENERAL.—Not later than 18
9 months after the date of enactment of this sec-
10 tion, the Secretary shall specify through rule-
11 making a standard format for entities providing
12 pharmacy benefit management services on be-
13 half of group health plans and health insurance
14 issuers offering group health insurance cov-
15 erage, to submit reports required under para-
16 graph (1).

17 “(B) ADDITIONAL REGULATIONS.—Not
18 later than 18 months after the date of enact-
19 ment of this section, the Secretary shall,
20 through rulemaking, promulgate any other final
21 regulations necessary to implement the require-
22 ments of this section. In promulgating such
23 regulations, the Secretary shall, to the extent
24 practicable, align the reporting requirements

1 under this section with the reporting require-
2 ments under section 2799A-10.

3 “(c) REQUIREMENT TO PROVIDE INFORMATION TO
4 PARTICIPANTS OR BENEFICIARIES.—A group health plan,
5 including with respect to group health insurance coverage
6 offered in connection with a group health plan, upon re-
7 quest of a participant or beneficiary, shall provide to such
8 participant or beneficiary—

9 “(1) the summary document described in sub-
10 section (b)(2)(B)(ii); and

11 “(2) the information described in subsection
12 (b)(2)(A)(i)(III) with respect to a claim made by or
13 on behalf of such participant or beneficiary.

14 “(d) ENFORCEMENT.—

15 “(1) IN GENERAL.—The Secretary shall enforce
16 this section. The enforcement authority under this
17 subsection shall apply only with respect to group
18 health plans (including group health insurance cov-
19 erage offered in connection with such a plan) to
20 which the requirements of subparts I and II of part
21 A and part D apply in accordance with section 2722,
22 and with respect to entities providing pharmacy ben-
23 efit management services on behalf of such plans
24 and applicable entities providing services on behalf
25 of such plans.

1 “(2) FAILURE TO PROVIDE INFORMATION.—A
2 group health plan, a health insurance issuer offering
3 group health insurance coverage, an entity providing
4 pharmacy benefit management services on behalf of
5 such a plan or issuer, or an applicable entity pro-
6 viding services on behalf of such a plan or issuer
7 that violates subsection (a); an entity providing
8 pharmacy benefit management services on behalf of
9 such a plan or issuer that fails to provide the infor-
10 mation required under subsection (b); or a group
11 health plan that fails to provide the information re-
12 quired under subsection (c), shall be subject to a
13 civil monetary penalty in the amount of \$10,000 for
14 each day during which such violation continues or
15 such information is not disclosed or reported.

16 “(3) FALSE INFORMATION.—A health insurance
17 issuer, an entity providing pharmacy benefit man-
18 agement services, or a third party administrator pro-
19 viding services on behalf of such issuer offered by a
20 health insurance issuer that knowingly provides false
21 information under this section shall be subject to a
22 civil monetary penalty in an amount not to exceed
23 \$100,000 for each item of false information. Such
24 civil monetary penalty shall be in addition to other
25 penalties as may be prescribed by law.

1 “(4) 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 monetary penalties under this subsection in the
6 same manner as such provisions apply to a penalty
7 or proceeding under such section.

8 “(5) WAIVERS.—The Secretary may waive pen-
9 alties under paragraph (2), or extend the period of
10 time for compliance with a requirement of this sec-
11 tion, for an entity in violation of this section that
12 has made a good-faith effort to comply with the re-
13 quirements in this section.

14 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
15 tion shall be construed to permit a health insurance issuer,
16 group health plan, entity providing pharmacy benefit man-
17 agement services on behalf of a group health plan or
18 health insurance issuer, or other entity to restrict disclo-
19 sure to, or otherwise limit the access of, the Secretary to
20 a report described in subsection (b)(1) or information re-
21 lated to compliance with subsections (a), (b), (c), or (d)
22 by such issuer, plan, or entity.

23 “(f) DEFINITIONS.—In this section:

24 “(1) APPLICABLE ENTITY.—The term ‘applica-
25 ble entity’ means—

1 “(A) an applicable group purchasing orga-
 2 nization, drug manufacturer, distributor, whole-
 3 saler, rebate aggregator (or other purchasing
 4 entity designed to aggregate rebates), or associ-
 5 ated third party;

6 “(B) any subsidiary, parent, affiliate, or
 7 subcontractor of a group health plan, health in-
 8 surance issuer, entity that provides pharmacy
 9 benefit management services on behalf of such
 10 a plan or issuer, or any entity described in sub-
 11 paragraph (A); or

12 “(C) such other entity as the Secretary
 13 may specify through rulemaking.

14 “(2) APPLICABLE GROUP PURCHASING ORGANI-
 15 ZATION.—The term ‘applicable group purchasing or-
 16 ganization’ means a group purchasing organization
 17 that is affiliated with or under common ownership
 18 with an entity providing pharmacy benefit manage-
 19 ment services.

20 “(3) CONTRACTED COMPENSATION.—The term
 21 ‘contracted compensation’ means the sum of any in-
 22 gredient cost and dispensing fee for a drug (inclusive
 23 of the out-of-pocket costs to the participant or bene-
 24 ficiary), or another analogous compensation struc-

1 ture that the Secretary may specify through regula-
2 tions.

3 “(4) GROSS SPENDING.—The term ‘gross
4 spending’, with respect to prescription drug benefits
5 under a group health plan or health insurance cov-
6 erage, means the amount spent by a group health
7 plan or health insurance issuer on prescription drug
8 benefits, calculated before the application of rebates,
9 fees, alternative discounts, or other remuneration.

10 “(5) NET SPENDING.—The term ‘net spending’,
11 with respect to prescription drug benefits under a
12 group health plan or health insurance coverage,
13 means the amount spent by a group health plan or
14 health insurance issuer on prescription drug bene-
15 fits, calculated after the application of rebates, fees,
16 alternative discounts, or other remuneration.

17 “(6) PLAN SPONSOR.—The term ‘plan sponsor’
18 has the meaning given such term in section 3(16)(B)
19 of the Employee Retirement Income Security Act of
20 1974.

21 “(7) REMUNERATION.—The term ‘remunera-
22 tion’ has the meaning given such term by the Sec-
23 retary through rulemaking, which shall be reeval-
24 ated by the Secretary every 5 years.

1 “(8) SPECIFIED LARGE EMPLOYER.—The term
2 ‘specified large employer’ means, in connection with
3 a group health plan (including group health insur-
4 ance coverage offered in connection with such a
5 plan) established or maintained by a single em-
6 ployer, with respect to a calendar year or a plan
7 year, as applicable, an employer who employed an
8 average of at least 100 employees on business days
9 during the preceding calendar year or plan year and
10 who employs at least 1 employee on the first day of
11 the calendar year or plan year.

12 “(9) SPECIFIED LARGE PLAN.—The term ‘spec-
13 ified large plan’ means a group health plan (includ-
14 ing group health insurance coverage offered in con-
15 nection with such a plan) established or maintained
16 by a plan sponsor described in clause (ii) or (iii) of
17 section 3(16)(B) of the Employee Retirement In-
18 come Security Act of 1974 that had an average of
19 at least 100 participants on business days during
20 the preceding calendar year or plan year, as applica-
21 ble.

22 “(10) WHOLESALE ACQUISITION COST.—The
23 term ‘wholesale acquisition cost’ has the meaning
24 given such term in section 1847A(c)(6)(B) of the
25 Social Security Act.”; and

1 (2) in section 2723 (42 U.S.C. 300gg-22)—

2 (A) in subsection (a)—

3 (i) in paragraph (1), by inserting
4 “(other than section 2799A-11)” after
5 “part D”; and

6 (ii) in paragraph (2), by inserting
7 “(other than section 2799A-11)” after
8 “part D”; and

9 (B) in subsection (b)—

10 (i) in paragraph (1), by inserting
11 “(other than section 2799A-11)” after
12 “part D”;

13 (ii) in paragraph (2)(A), by inserting
14 “(other than section 2799A-11)” after
15 “part D”; and

16 (iii) in paragraph (2)(C)(ii), by insert-
17 ing “(other than section 2799A-11)” after
18 “part D”.

19 (b) EMPLOYEE RETIREMENT INCOME SECURITY ACT
20 OF 1974.—

21 (1) IN GENERAL.—Subtitle B of title I of the
22 Employee Retirement Income Security Act of 1974
23 (29 U.S.C. 1021 et seq.) is amended—

1 (A) in subpart B of part 7 (29 U.S.C.
2 1185 et seq.), by adding at the end the fol-
3 lowing:

4 **“SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**
5 **MACY BENEFIT MANAGEMENT SERVICES.**

6 “(a) IN GENERAL.—For plan years beginning on or
7 after the date that is 30 months after the date of enact-
8 ment of this section (referred to in this subsection and
9 subsection (b) as the ‘effective date’), a group health plan
10 or a health insurance issuer offering group health insur-
11 ance coverage, or an entity providing pharmacy benefit
12 management services on behalf of such a plan or issuer,
13 shall not enter into a contract, including an extension or
14 renewal of a contract, entered into on or after the effective
15 date, with an applicable entity unless such applicable enti-
16 ty agrees to—

17 “(1) not limit or delay the disclosure of infor-
18 mation to the group health plan (including such a
19 plan offered through a health insurance issuer) in
20 such a manner that prevents an entity providing
21 pharmacy benefit management services on behalf of
22 a group health plan or health insurance issuer offer-
23 ing group health insurance coverage from making
24 the reports described in subsection (b); and

1 “(2) provide the entity providing pharmacy ben-
2 efit management services on behalf of a group health
3 plan or health insurance issuer relevant information
4 necessary to make the reports described in sub-
5 section (b).

6 “(b) REPORTS.—

7 “(1) IN GENERAL.—For plan years beginning
8 on or after the effective date, in the case of any con-
9 tract between a group health plan or a health insur-
10 ance issuer offering group health insurance coverage
11 offered in connection with such a plan and an entity
12 providing pharmacy benefit management services on
13 behalf of such plan or issuer, including an extension
14 or renewal of such a contract, entered into on or
15 after the effective date, the entity providing phar-
16 macy benefit management services on behalf of such
17 a group health plan or health insurance issuer, not
18 less frequently than every 6 months (or, at the re-
19 quest of a group health plan, not less frequently
20 than quarterly, and under the same conditions,
21 terms, and cost of the semiannual report under this
22 subsection), shall submit to the group health plan a
23 report in accordance with this section. Each such re-
24 port shall be made available to such group health
25 plan in plain language, in a machine-readable for-

1 mat, and as the Secretary may determine, other for-
2 mats. Each such report shall include the information
3 described in paragraph (2).

4 “(2) INFORMATION DESCRIBED.—For purposes
5 of paragraph (1), the information described in this
6 paragraph is, with respect to drugs covered by a
7 group health plan or group health insurance cov-
8 erage offered by a health insurance issuer in connec-
9 tion with a group health plan during each reporting
10 period—

11 “(A) in the case of a group health plan
12 that is offered by a specified large employer or
13 that is a specified large plan, and is not offered
14 as health insurance coverage, or in the case of
15 health insurance coverage for which the election
16 under paragraph (3) is made for the applicable
17 reporting period—

18 “(i) a list of drugs for which a claim
19 was filed and, with respect to each such
20 drug on such list—

21 “(I) the contracted compensation
22 paid by the group health plan or
23 health insurance issuer for each cov-
24 ered drug (identified by the National
25 Drug Code) to the entity providing

1 pharmacy benefit management serv-
2 ices or other applicable entity on be-
3 half of the group health plan or health
4 insurance issuer;

5 “(II) the contracted compensa-
6 tion paid to the pharmacy, by any en-
7 tity providing pharmacy benefit man-
8 agement services or other applicable
9 entity on behalf of the group health
10 plan or health insurance issuer, for
11 each covered drug (identified by the
12 National Drug Code);

13 “(III) for each such claim, the
14 difference between the amount paid
15 under subclause (I) and the amount
16 paid under subclause (II);

17 “(IV) the proprietary name, es-
18 tablished name or proper name, and
19 the National Drug Code;

20 “(V) for each claim for the drug
21 (including original prescriptions and
22 refills) and for each dosage unit of the
23 drug for which a claim was filed, the
24 type of dispensing channel used to

1 furnish the drug, including retail, mail
2 order, or specialty pharmacy;

3 “(VI) with respect to each drug
4 dispensed, for each type of dispensing
5 channel (including retail, mail order,
6 or specialty pharmacy)—

7 “(aa) whether such drug is a
8 brand name drug or a generic
9 drug, and—

10 “(AA) in the case of a
11 brand name drug, the whole-
12 sale acquisition cost, listed
13 as cost per days supply and
14 cost per dosage unit, on the
15 date such drug was dis-
16 pensed; and

17 “(BB) in the case of a
18 generic drug, the average
19 wholesale price, listed as
20 cost per days supply and
21 cost per dosage unit, on the
22 date such drug was dis-
23 pensed; and

24 “(bb) the total number of—

1 “(AA) prescription
2 claims (including original
3 prescriptions and refills);

4 “(BB) participants and
5 beneficiaries for whom a
6 claim for such drug was
7 filed through the applicable
8 dispensing channel;

9 “(CC) dosage units and
10 dosage units per fill of such
11 drug; and

12 “(DD) days supply of
13 such drug per fill;

14 “(VII) the net price per course of
15 treatment or single fill, such as a 30-
16 day supply or 90-day supply to the
17 plan or coverage after rebates, fees,
18 alternative discounts, or other remun-
19 eration received from applicable enti-
20 ties;

21 “(VIII) the total amount of out-
22 of-pocket spending by participants
23 and beneficiaries on such drug, in-
24 cluding spending through copayments,
25 coinsurance, and deductibles, but not

1 including any amounts spent by par-
2 ticipants and beneficiaries on drugs
3 not covered under the plan or cov-
4 erage, or for which no claim is sub-
5 mitted under the plan or coverage;

6 “(IX) the total net spending on
7 the drug;

8 “(X) the total amount received,
9 or expected to be received, by the plan
10 or issuer from any applicable entity in
11 rebates, fees, alternative discounts, or
12 other remuneration;

13 “(XI) the total amount received,
14 or expected to be received, by the enti-
15 ty providing pharmacy benefit man-
16 agement services, from applicable en-
17 tities, in rebates, fees, alternative dis-
18 counts, or other remuneration from
19 such entities—

20 “(aa) for claims incurred
21 during the reporting period; and

22 “(bb) that is related to utili-
23 zation of such drug or spending
24 on such drug; and

1 “(XII) to the extent feasible, in-
2 formation on the total amount of re-
3 muneration for such drug, including
4 copayment assistance dollars paid, co-
5 payment cards applied, or other dis-
6 counts provided by each drug manu-
7 facturer (or entity administering co-
8 payment assistance on behalf of such
9 drug manufacturer), to the partici-
10 pants and beneficiaries enrolled in
11 such plan or coverage;

12 “(ii) a list of each therapeutic class
13 (as defined by the Secretary) for which a
14 claim was filed under the group health
15 plan or health insurance coverage during
16 the reporting period, and, with respect to
17 each such therapeutic class—

18 “(I) the total gross spending on
19 drugs in such class before rebates,
20 price concessions, alternative dis-
21 counts, or other remuneration from
22 applicable entities;

23 “(II) the net spending in such
24 class after such rebates, price conces-

1 sions, alternative discounts, or other
2 remuneration from applicable entities;

3 “(III) the total amount received,
4 or expected to be received, by the enti-
5 ty providing pharmacy benefit man-
6 agement services, from applicable en-
7 tities, in rebates, fees, alternative dis-
8 counts, or other remuneration from
9 such entities—

10 “(aa) for claims incurred
11 during the reporting period; and

12 “(bb) that is related to utili-
13 zation of drugs or drug spending;

14 “(IV) the average net spending
15 per 30-day supply and per 90-day
16 supply by the plan or by the issuer
17 with respect to such coverage and its
18 participants and beneficiaries, among
19 all drugs within the therapeutic class
20 for which a claim was filed during the
21 reporting period;

22 “(V) the number of participants
23 and beneficiaries who filled a prescrip-
24 tion for a drug in such class, includ-

1 ing the National Drug Code for each
2 such drug;

3 “(VI) if applicable, a description
4 of the formulary tiers and utilization
5 mechanisms (such as prior authoriza-
6 tion or step therapy) employed for
7 drugs in that class; and

8 “(VII) the total out-of-pocket
9 spending under the plan or coverage
10 by participants and beneficiaries, in-
11 cluding spending through copayments,
12 coinsurance, and deductibles, but not
13 including any amounts spent by par-
14 ticipants and beneficiaries on drugs
15 not covered under the plan or cov-
16 erage or for which no claim is sub-
17 mitted under the plan or coverage;

18 “(iii) with respect to any drug for
19 which gross spending under the group
20 health plan or health insurance coverage
21 exceeded \$10,000 during the reporting pe-
22 riod or, in the case that gross spending
23 under the group health plan or coverage
24 exceeded \$10,000 during the reporting pe-
25 riod with respect to fewer than 50 drugs,

1 with respect to the 50 prescription drugs
2 with the highest spending during the re-
3 porting period—

4 “(I) a list of all other drugs in
5 the same therapeutic class as such
6 drug;

7 “(II) if applicable, the rationale
8 for the formulary placement of such
9 drug in that therapeutic category or
10 class, selected from a list of standard
11 rationales established by the Sec-
12 retary, in consultation with stake-
13 holders; and

14 “(III) any change in formulary
15 placement compared to the prior plan
16 year; and

17 “(iv) in the case that such plan or
18 issuer (or an entity providing pharmacy
19 benefit management services on behalf of
20 such plan or issuer) has an affiliated phar-
21 macy or pharmacy under common owner-
22 ship, including mandatory mail and spe-
23 cialty home delivery programs, retail and
24 mail auto-refill programs, and cost sharing

1 assistance incentives funded by an entity
2 providing pharmacy benefit services—

3 “(I) an explanation of any ben-
4 efit design parameters that encourage
5 or require participants and bene-
6 ficiaries in the plan or coverage to fill
7 prescriptions at mail order, specialty,
8 or retail pharmacies;

9 “(II) the percentage of total pre-
10 scriptions dispensed by such phar-
11 macies to participants or beneficiaries
12 in such plan or coverage; and

13 “(III) a list of all drugs dis-
14 pensed by such pharmacies to partici-
15 pants or beneficiaries enrolled in such
16 plan or coverage, and, with respect to
17 each drug dispensed—

18 “(aa) the amount charged,
19 per dosage unit, per 30-day sup-
20 ply, or per 90-day supply (as ap-
21 plicable) to the plan or issuer,
22 and to participants and bene-
23 ficiaries;

24 “(bb) the median amount
25 charged to such plan or issuer,

1 and the interquartile range of the
2 costs, per dosage unit, per 30-
3 day supply, and per 90-day sup-
4 ply, including amounts paid by
5 the participants and bene-
6 ficiaries, when the same drug is
7 dispensed by other pharmacies
8 that are not affiliated with or
9 under common ownership with
10 the entity and that are included
11 in the pharmacy network of such
12 plan or coverage;

13 “(cc) the lowest cost per
14 dosage unit, per 30-day supply
15 and per 90-day supply, for each
16 such drug, including amounts
17 charged to the plan or coverage
18 and to participants and bene-
19 ficiaries, that is available from
20 any pharmacy included in the
21 network of such plan or coverage;
22 and

23 “(dd) the net acquisition
24 cost per dosage unit, per 30-day
25 supply, and per 90-day supply, if

1 such drug is subject to a max-
2 imum price discount; and

3 “(B) with respect to any group health
4 plan, including group health insurance coverage
5 offered in connection with such a plan, regard-
6 less of whether the plan or coverage is offered
7 by a specified large employer or whether it is a
8 specified large plan—

9 “(i) a summary document for the
10 group health plan that includes such infor-
11 mation described in clauses (i) through (iv)
12 of subparagraph (A), as specified by the
13 Secretary through guidance, program in-
14 struction, or otherwise (with no require-
15 ment of notice and comment rulemaking),
16 that the Secretary determines useful to
17 group health plans for purposes of select-
18 ing pharmacy benefit management serv-
19 ices, such as an estimated net price to
20 group health plan and participant or bene-
21 ficiary, a cost per claim, the fee structure
22 or reimbursement model, and estimated
23 cost per participant or beneficiary;

24 “(ii) a summary document for plans
25 and issuers to provide to participants and

1 beneficiaries, which shall be made available
2 to participants or beneficiaries upon re-
3 quest to their group health plan (including
4 in the case of group health insurance cov-
5 erage offered in connection with such a
6 plan), that—

7 “(I) contains such information
8 described in clauses (iii), (iv), (v), and
9 (vi), as applicable, as specified by the
10 Secretary through guidance, program
11 instruction, or otherwise (with no re-
12 quirement of notice and comment
13 rulemaking) that the Secretary deter-
14 mines useful to participants or bene-
15 ficiaries in better understanding the
16 plan or coverage or benefits under
17 such plan or coverage;

18 “(II) contains only aggregate in-
19 formation; and

20 “(III) states that participants
21 and beneficiaries may request specific,
22 claims-level information required to be
23 furnished under subsection (c) from
24 the group health plan or health insur-
25 ance issuer; and

1 “(iii) with respect to drugs covered by
2 such plan or coverage during such report-
3 ing period—

4 “(I) the total net spending by the
5 plan or coverage for all such drugs;

6 “(II) the total amount received,
7 or expected to be received, by the plan
8 or issuer from any applicable entity in
9 rebates, fees, alternative discounts, or
10 other remuneration; and

11 “(III) to the extent feasible, in-
12 formation on the total amount of re-
13 muneration for such drugs, including
14 copayment assistance dollars paid, co-
15 payment cards applied, or other dis-
16 counts provided by each drug manu-
17 facturer (or entity administering co-
18 payment assistance on behalf of such
19 drug manufacturer) to participants
20 and beneficiaries;

21 “(iv) amounts paid directly or indi-
22 rectly in rebates, fees, or any other type of
23 compensation (as defined in section
24 408(b)(2)(B)(ii)(dd)(AA)) to brokerage

1 firms, brokers, consultants, advisors, or
2 any other individual or firm, for—

3 “(I) the referral of the group
4 health plan’s or health insurance
5 issuer’s business to an entity pro-
6 viding pharmacy benefit management
7 services, including the identity of the
8 recipient of such amounts;

9 “(II) consideration of the entity
10 providing pharmacy benefit manage-
11 ment services by the group health
12 plan or health insurance issuer; or

13 “(III) the retention of the entity
14 by the group health plan or health in-
15 surance issuer;

16 “(v) an explanation of any benefit de-
17 sign parameters that encourage or require
18 participants and beneficiaries in such plan
19 or coverage to fill prescriptions at mail
20 order, specialty, or retail pharmacies that
21 are affiliated with or under common own-
22 ership with the entity providing pharmacy
23 benefit management services under such
24 plan or coverage, including mandatory mail
25 and specialty home delivery programs, re-

tail and mail auto-refill programs, and
 cost-sharing assistance incentives directly
 or indirectly funded by such entity; and

“(vi) total gross spending on all drugs
 under the plan or coverage during the re-
 porting period.

“(3) OPT-IN FOR GROUP HEALTH INSURANCE
 COVERAGE OFFERED BY A SPECIFIED LARGE EM-
 PLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In
 the case of group health insurance coverage offered
 in connection with a group health plan that is of-
 fered by a specified large employer or is a specified
 large plan, such group health plan may, on an an-
 nual basis, for plan years beginning on or after the
 date that is 30 months after the date of enactment
 of this section, elect to require an entity providing
 pharmacy benefit management services on behalf of
 the health insurance issuer to submit to such group
 health plan a report that includes all of the informa-
 tion described in paragraph (2)(A), in addition to
 the information described in paragraph (2)(B).

“(4) PRIVACY REQUIREMENTS.—

“(A) IN GENERAL.—An entity providing
 pharmacy benefit management services on be-
 half of a group health plan or a health insur-

1 ance issuer offering group health insurance cov-
 2 erage shall report information under paragraph
 3 (1) in a manner consistent with the privacy reg-
 4 ulations promulgated under section 13402(a) of
 5 the Health Information Technology for Eco-
 6 nomic and Clinical Health Act (42 U.S.C.
 7 17932(a)) and consistent with the privacy regu-
 8 lations promulgated under the Health Insur-
 9 ance Portability and Accountability Act of 1996
 10 in part 160 and subparts A and E of part 164
 11 of title 45, Code of Federal Regulations (or suc-
 12 cessor regulations) (referred to in this para-
 13 graph as the ‘HIPAA privacy regulations’) and
 14 shall restrict the use and disclosure of such in-
 15 formation according to such privacy regulations
 16 and such HIPAA privacy regulations.

17 “(B) ADDITIONAL REQUIREMENTS.—

18 “(i) IN GENERAL.—An entity pro-
 19 viding pharmacy benefit management serv-
 20 ices on behalf of a group health plan or
 21 health insurance issuer offering group
 22 health insurance coverage that submits a
 23 report under paragraph (1) shall ensure
 24 that such report contains only summary
 25 health information, as defined in section

1 164.504(a) of title 45, Code of Federal
2 Regulations (or successor regulations).

3 “(ii) RESTRICTIONS.—In carrying out
4 this subsection, a group health plan shall
5 comply with section 164.504(f) of title 45,
6 Code of Federal Regulations (or a suc-
7 cessor regulation), and a plan sponsor shall
8 act in accordance with the terms of the
9 agreement described in such section.

10 “(C) RULE OF CONSTRUCTION.—

11 “(i) Nothing in this section shall be
12 construed to modify the requirements for
13 the creation, receipt, maintenance, or
14 transmission of protected health informa-
15 tion under the HIPAA privacy regulations.

16 “(ii) Nothing in this section shall be
17 construed to affect the application of any
18 Federal or State privacy or civil rights law,
19 including the HIPAA privacy regulations,
20 the Genetic Information Nondiscrimination
21 Act of 2008 (Public Law 110–233) (in-
22 cluding the amendments made by such
23 Act), the Americans with Disabilities Act
24 of 1990 (42 U.S.C. 12101 et seq.), section
25 504 of the Rehabilitation Act of 1973 (29

1 U.S.C. 794), section 1557 of the Patient
2 Protection and Affordable Care Act (42
3 U.S.C. 18116), title VI of the Civil Rights
4 Act of 1964 (42 U.S.C. 2000d), and title
5 VII of the Civil Rights Act of 1964 (42
6 U.S.C. 2000e).

7 “(D) WRITTEN NOTICE.—Each plan year,
8 group health plans, including with respect to
9 group health insurance coverage offered in con-
10 nection with a group health plan, shall provide
11 to each participant or beneficiary written notice
12 informing the participant or beneficiary of the
13 requirement for entities providing pharmacy
14 benefit management services on behalf of the
15 group health plan or health insurance issuer of-
16 fering group health insurance coverage to sub-
17 mit reports to group health plans under para-
18 graph (1), as applicable, which may include in-
19 corporating such notification in plan documents
20 provided to the participant or beneficiary, or
21 providing individual notification.

22 “(E) LIMITATION TO BUSINESS ASSOCI-
23 ATES.—A group health plan receiving a report
24 under paragraph (1) may disclose such informa-
25 tion only to the entity from which the report

1 was received or to that entity's business associ-
 2 ates as defined in section 160.103 of title 45,
 3 Code of Federal Regulations (or successor regu-
 4 lations) or as permitted by the HIPAA privacy
 5 regulations.

6 “(F) CLARIFICATION REGARDING PUBLIC
 7 DISCLOSURE OF INFORMATION.—Nothing in
 8 this section shall prevent an entity providing
 9 pharmacy benefit management services on be-
 10 half of a group health plan or health insurance
 11 issuer offering group health insurance coverage,
 12 from placing reasonable restrictions on the pub-
 13 lic disclosure of the information contained in a
 14 report described in paragraph (1), except that
 15 such plan, issuer, or entity may not—

16 “(i) restrict disclosure of such report
 17 to the Department of Health and Human
 18 Services, the Department of Labor, or the
 19 Department of the Treasury; or

20 “(ii) prevent disclosure for the pur-
 21 poses of subsection (c), or any other public
 22 disclosure requirement under this section.

23 “(G) LIMITED FORM OF REPORT.—The
 24 Secretary shall define through rulemaking a
 25 limited form of the report under paragraph (1)

1 required with respect to any group health plan
2 established by a plan sponsor that is, or is af-
3 filiated with, a drug manufacturer, drug whole-
4 saler, or other direct participant in the drug
5 supply chain, in order to prevent anti-competi-
6 tive behavior.

7 “(5) STANDARD FORMAT AND REGULATIONS.—

8 “(A) IN GENERAL.—Not later than 18
9 months after the date of enactment of this sec-
10 tion, the Secretary shall specify through rule-
11 making a standard format for entities providing
12 pharmacy benefit management services on be-
13 half of group health plans and health insurance
14 issuers offering group health insurance cov-
15 erage, to submit reports required under para-
16 graph (1).

17 “(B) ADDITIONAL REGULATIONS.—Not
18 later than 18 months after the date of enact-
19 ment of this section, the Secretary shall,
20 through rulemaking, promulgate any other final
21 regulations necessary to implement the require-
22 ments of this section. In promulgating such
23 regulations, the Secretary shall, to the extent
24 practicable, align the reporting requirements

1 under this section with the reporting require-
2 ments under section 725.

3 “(c) REQUIREMENT TO PROVIDE INFORMATION TO
4 PARTICIPANTS OR BENEFICIARIES.—A group health plan,
5 including with respect to group health insurance coverage
6 offered in connection with a group health plan, upon re-
7 quest of a participant or beneficiary, shall provide to such
8 participant or beneficiary—

9 “(1) the summary document described in sub-
10 section (b)(2)(B)(ii); and

11 “(2) the information described in subsection
12 (b)(2)(A)(i)(III) with respect to a claim made by or
13 on behalf of such participant or beneficiary.

14 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
15 tion shall be construed to permit a health insurance issuer,
16 group health plan, entity providing pharmacy benefit man-
17 agement services on behalf of a group health plan or
18 health insurance issuer, or other entity to restrict dislo-
19 sure to, or otherwise limit the access of, the Secretary to
20 a report described in subsection (b)(1) or information re-
21 lated to compliance with subsections (a), (b), or (c) of this
22 section or section 502(c)(13) by such issuer, plan, or enti-
23 ty.

24 “(e) DEFINITIONS.—In this section:

1 “(1) APPLICABLE ENTITY.—The term ‘applica-
2 ble entity’ means—

3 “(A) an applicable group purchasing orga-
4 nization, drug manufacturer, distributor, whole-
5 saler, rebate aggregator (or other purchasing
6 entity designed to aggregate rebates), or associ-
7 ated third party;

8 “(B) any subsidiary, parent, affiliate, or
9 subcontractor of a group health plan, health in-
10 surance issuer, entity that provides pharmacy
11 benefit management services on behalf of such
12 a plan or issuer, or any entity described in sub-
13 paragraph (A); or

14 “(C) such other entity as the Secretary
15 may specify through rulemaking.

16 “(2) APPLICABLE GROUP PURCHASING ORGANI-
17 ZATION.—The term ‘applicable group purchasing or-
18 ganization’ means a group purchasing organization
19 that is affiliated with or under common ownership
20 with an entity providing pharmacy benefit manage-
21 ment services.

22 “(3) CONTRACTED COMPENSATION.—The term
23 ‘contracted compensation’ means the sum of any in-
24 gredient cost and dispensing fee for a drug (inclusive
25 of the out-of-pocket costs to the participant or bene-

1 ficiary), or another analogous compensation struc-
2 ture that the Secretary may specify through regula-
3 tions.

4 “(4) GROSS SPENDING.—The term ‘gross
5 spending’, with respect to prescription drug benefits
6 under a group health plan or health insurance cov-
7 erage, means the amount spent by a group health
8 plan or health insurance issuer on prescription drug
9 benefits, calculated before the application of rebates,
10 fees, alternative discounts, or other remuneration.

11 “(5) NET SPENDING.—The term ‘net spending’,
12 with respect to prescription drug benefits under a
13 group health plan or health insurance coverage,
14 means the amount spent by a group health plan or
15 health insurance issuer on prescription drug bene-
16 fits, calculated after the application of rebates, fees,
17 alternative discounts, or other remuneration.

18 “(6) PLAN SPONSOR.—The term ‘plan sponsor’
19 has the meaning given such term in section
20 3(16)(B).

21 “(7) REMUNERATION.—The term ‘remunera-
22 tion’ has the meaning given such term by the Sec-
23 retary through rulemaking, which shall be reeval-
24 ated by the Secretary every 5 years.

1 “(8) SPECIFIED LARGE EMPLOYER.—The term
 2 ‘specified large employer’ means, in connection with
 3 a group health plan (including group health insur-
 4 ance coverage offered in connection with such a
 5 plan) established or maintained by a single em-
 6 ployer, with respect to a calendar year or a plan
 7 year, as applicable, an employer who employed an
 8 average of at least 100 employees on business days
 9 during the preceding calendar year or plan year and
 10 who employs at least 1 employee on the first day of
 11 the calendar year or plan year.

12 “(9) SPECIFIED LARGE PLAN.—The term ‘spec-
 13 ified large plan’ means a group health plan (includ-
 14 ing group health insurance coverage offered in con-
 15 nection with such a plan) established or maintained
 16 by a plan sponsor described in clause (ii) or (iii) of
 17 section 3(16)(B) that had an average of at least 100
 18 participants on business days during the preceding
 19 calendar year or plan year, as applicable.

20 “(10) WHOLESALE ACQUISITION COST.—The
 21 term ‘wholesale acquisition cost’ has the meaning
 22 given such term in section 1847A(c)(6)(B) of the
 23 Social Security Act (42 U.S.C. 1395w-
 24 3a(c)(6)(B)).”;

25 (B) in section 502 (29 U.S.C. 1132)—

1 (i) in subsection (a)(6), by striking
2 “or (9)” and inserting “(9), or (13)”;

3 (ii) in subsection (b)(3), by striking
4 “under subsection (c)(9)” and inserting
5 “under paragraphs (9) and (13) of sub-
6 section (c)”;

7 (iii) in subsection (c), by adding at
8 the end the following:

9 “(13) SECRETARIAL ENFORCEMENT AUTHORITY
10 RELATING TO OVERSIGHT OF PHARMACY BENEFIT
11 MANAGEMENT SERVICES.—

12 “(A) FAILURE TO PROVIDE INFORMA-
13 TION.—The Secretary may impose a penalty
14 against a plan administrator of a group health
15 plan, a health insurance issuer offering group
16 health insurance coverage, or an entity pro-
17 viding pharmacy benefit management services
18 on behalf of such a plan or issuer, or an appli-
19 cable entity (as defined in section 726(f)) that
20 violates section 726(a); an entity providing
21 pharmacy benefit management services on be-
22 half of such a plan or issuer that fails to pro-
23 vide the information required under section
24 726(b); or any person who causes a group
25 health plan to fail to provide the information

1 required under section 726(c), in the amount of
2 \$10,000 for each day during which such viola-
3 tion continues or such information is not dis-
4 closed or reported.

5 “(B) FALSE INFORMATION.—The Sec-
6 retary may impose a penalty against a plan ad-
7 ministrator of a group health plan, a health in-
8 surance issuer offering group health insurance
9 coverage, an entity providing pharmacy benefit
10 management services, or an applicable entity
11 (as defined in section 726(f)) that knowingly
12 provides false information under section 726, in
13 an amount not to exceed \$100,000 for each
14 item of false information. Such penalty shall be
15 in addition to other penalties as may be pre-
16 scribed by law.

17 “(C) WAIVERS.—The Secretary may waive
18 penalties under subparagraph (A), or extend
19 the period of time for compliance with a re-
20 quirement of this section, for an entity in viola-
21 tion of section 726 that has made a good-faith
22 effort to comply with the requirements of sec-
23 tion 726.”; and

1 (C) in section 732(a) (29 U.S.C.
 2 1191a(a)), by striking “section 711” and in-
 3 serting “sections 711 and 726”.

4 (2) CLERICAL AMENDMENT.—The table of con-
 5 tents in section 1 of the Employee Retirement In-
 6 come Security Act of 1974 (29 U.S.C. 1001 et seq.)
 7 is amended by inserting after the item relating to
 8 section 725 the following new item:

“Sec. 726. Oversight of entities that provide pharmacy benefit management
 services.”.

9 (c) INTERNAL REVENUE CODE OF 1986.—

10 (1) IN GENERAL.—Chapter 100 of the Internal
 11 Revenue Code of 1986 is amended—

12 (A) by adding at the end of subchapter B
 13 the following:

14 **“SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**
 15 **MACY BENEFIT MANAGEMENT SERVICES.**

16 “(a) IN GENERAL.—For plan years beginning on or
 17 after the date that is 30 months after the date of enact-
 18 ment of this section (referred to in this subsection and
 19 subsection (b) as the ‘effective date’), a group health plan,
 20 or an entity providing pharmacy benefit management serv-
 21 ices on behalf of such a plan, shall not enter into a con-
 22 tract, including an extension or renewal of a contract, en-
 23 tered into on or after the effective date, with an applicable
 24 entity unless such applicable entity agrees to—

1 “(1) not limit or delay the disclosure of infor-
2 mation to the group health plan in such a manner
3 that prevents an entity providing pharmacy benefit
4 management services on behalf of a group health
5 plan from making the reports described in sub-
6 section (b); and

7 “(2) provide the entity providing pharmacy ben-
8 efit management services on behalf of a group health
9 plan relevant information necessary to make the re-
10 ports described in subsection (b).

11 “(b) REPORTS.—

12 “(1) IN GENERAL.—For plan years beginning
13 on or after the effective date, in the case of any con-
14 tract between a group health plan and an entity pro-
15 viding pharmacy benefit management services on be-
16 half of such plan, including an extension or renewal
17 of such a contract, entered into on or after the effec-
18 tive date, the entity providing pharmacy benefit
19 management services on behalf of such a group
20 health plan, not less frequently than every 6 months
21 (or, at the request of a group health plan, not less
22 frequently than quarterly, and under the same con-
23 ditions, terms, and cost of the semiannual report
24 under this subsection), shall submit to the group
25 health plan a report in accordance with this section.

1 Each such report shall be made available to such
2 group health plan in plain language, in a machine-
3 readable format, and as the Secretary may deter-
4 mine, other formats. Each such report shall include
5 the information described in paragraph (2).

6 “(2) INFORMATION DESCRIBED.—For purposes
7 of paragraph (1), the information described in this
8 paragraph is, with respect to drugs covered by a
9 group health plan during each reporting period—

10 “(A) in the case of a group health plan
11 that is offered by a specified large employer or
12 that is a specified large plan, and is not offered
13 as health insurance coverage, or in the case of
14 health insurance coverage for which the election
15 under paragraph (3) is made for the applicable
16 reporting period—

17 “(i) a list of drugs for which a claim
18 was filed and, with respect to each such
19 drug on such list—

20 “(I) the contracted compensation
21 paid by the group health plan for each
22 covered drug (identified by the Na-
23 tional Drug Code) to the entity pro-
24 viding pharmacy benefit management

1 services or other applicable entity on
2 behalf of the group health plan;

3 “(II) the contracted compensa-
4 tion paid to the pharmacy, by any en-
5 tity providing pharmacy benefit man-
6 agement services or other applicable
7 entity on behalf of the group health
8 plan, for each covered drug (identified
9 by the National Drug Code);

10 “(III) for each such claim, the
11 difference between the amount paid
12 under subclause (I) and the amount
13 paid under subclause (II);

14 “(IV) the proprietary name, es-
15 tablished name or proper name, and
16 the National Drug Code;

17 “(V) for each claim for the drug
18 (including original prescriptions and
19 refills) and for each dosage unit of the
20 drug for which a claim was filed, the
21 type of dispensing channel used to
22 furnish the drug, including retail, mail
23 order, or specialty pharmacy;

24 “(VI) with respect to each drug
25 dispensed, for each type of dispensing

1 channel (including retail, mail order,
2 or specialty pharmacy)—

3 “(aa) whether such drug is a
4 brand name drug or a generic
5 drug, and—

6 “(AA) in the case of a
7 brand name drug, the whole-
8 sale acquisition cost, listed
9 as cost per days supply and
10 cost per dosage unit, on the
11 date such drug was dis-
12 pensed; and

13 “(BB) in the case of a
14 generic drug, the average
15 wholesale price, listed as
16 cost per days supply and
17 cost per dosage unit, on the
18 date such drug was dis-
19 pensed; and

20 “(bb) the total number of—

21 “(AA) prescription
22 claims (including original
23 prescriptions and refills);

24 “(BB) participants and
25 beneficiaries for whom a

1 claim for such drug was
2 filed through the applicable
3 dispensing channel;

4 “(CC) dosage units and
5 dosage units per fill of such
6 drug; and

7 “(DD) days supply of
8 such drug per fill;

9 “(VII) the net price per course of
10 treatment or single fill, such as a 30-
11 day supply or 90-day supply to the
12 plan after rebates, fees, alternative
13 discounts, or other remuneration re-
14 ceived from applicable entities;

15 “(VIII) the total amount of out-
16 of-pocket spending by participants
17 and beneficiaries on such drug, in-
18 cluding spending through copayments,
19 coinsurance, and deductibles, but not
20 including any amounts spent by par-
21 ticipants and beneficiaries on drugs
22 not covered under the plan, or for
23 which no claim is submitted under the
24 plan;

1 “(IX) the total net spending on
2 the drug;

3 “(X) the total amount received,
4 or expected to be received, by the plan
5 from any applicable entity in rebates,
6 fees, alternative discounts, or other
7 remuneration;

8 “(XI) the total amount received,
9 or expected to be received, by the enti-
10 ty providing pharmacy benefit man-
11 agement services, from applicable en-
12 tities, in rebates, fees, alternative dis-
13 counts, or other remuneration from
14 such entities—

15 “(aa) for claims incurred
16 during the reporting period; and

17 “(bb) that is related to utili-
18 zation of such drug or spending
19 on such drug; and

20 “(XII) to the extent feasible, in-
21 formation on the total amount of re-
22 muneration for such drug, including
23 copayment assistance dollars paid, co-
24 payment cards applied, or other dis-
25 counts provided by each drug manu-

1 facturer (or entity administering co-
2 payment assistance on behalf of such
3 drug manufacturer), to the partici-
4 pants and beneficiaries enrolled in
5 such plan;

6 “(ii) a list of each therapeutic class
7 (as defined by the Secretary) for which a
8 claim was filed under the group health
9 plan during the reporting period, and, with
10 respect to each such therapeutic class—

11 “(I) the total gross spending on
12 drugs in such class before rebates,
13 price concessions, alternative dis-
14 counts, or other remuneration from
15 applicable entities;

16 “(II) the net spending in such
17 class after such rebates, price conces-
18 sions, alternative discounts, or other
19 remuneration from applicable entities;

20 “(III) the total amount received,
21 or expected to be received, by the enti-
22 ty providing pharmacy benefit man-
23 agement services, from applicable en-
24 tities, in rebates, fees, alternative dis-

1 counts, or other remuneration from
2 such entities—

3 “(aa) for claims incurred
4 during the reporting period; and

5 “(bb) that is related to utili-
6 zation of drugs or drug spending;

7 “(IV) the average net spending
8 per 30-day supply and per 90-day
9 supply by the plan and its partici-
10 pants and beneficiaries, among all
11 drugs within the therapeutic class for
12 which a claim was filed during the re-
13 porting period;

14 “(V) the number of participants
15 and beneficiaries who filled a prescrip-
16 tion for a drug in such class, includ-
17 ing the National Drug Code for each
18 such drug;

19 “(VI) if applicable, a description
20 of the formulary tiers and utilization
21 mechanisms (such as prior authoriza-
22 tion or step therapy) employed for
23 drugs in that class; and

24 “(VII) the total out-of-pocket
25 spending under the plan by partici-

1 pants and beneficiaries, including
2 spending through copayments, coin-
3 surance, and deductibles, but not in-
4 cluding any amounts spent by partici-
5 pants and beneficiaries on drugs not
6 covered under the plan or for which
7 no claim is submitted under the plan;
8 “(iii) with respect to any drug for
9 which gross spending under the group
10 health plan exceeded \$10,000 during the
11 reporting period or, in the case that gross
12 spending under the group health plan ex-
13 ceeded \$10,000 during the reporting pe-
14 riod with respect to fewer than 50 drugs,
15 with respect to the 50 prescription drugs
16 with the highest spending during the re-
17 porting period—
18 “(I) a list of all other drugs in
19 the same therapeutic class as such
20 drug;
21 “(II) if applicable, the rationale
22 for the formulary placement of such
23 drug in that therapeutic category or
24 class, selected from a list of standard
25 rationales established by the Sec-

1 retary, in consultation with stake-
2 holders; and

3 “(III) any change in formulary
4 placement compared to the prior plan
5 year; and

6 “(iv) in the case that such plan (or an
7 entity providing pharmacy benefit manage-
8 ment services on behalf of such plan) has
9 an affiliated pharmacy or pharmacy under
10 common ownership, including mandatory
11 mail and specialty home delivery programs,
12 retail and mail auto-refill programs, and
13 cost sharing assistance incentives funded
14 by an entity providing pharmacy benefit
15 services—

16 “(I) an explanation of any ben-
17 efit design parameters that encourage
18 or require participants and bene-
19 ficiaries in the plan to fill prescrip-
20 tions at mail order, specialty, or retail
21 pharmacies;

22 “(II) the percentage of total pre-
23 scriptions dispensed by such phar-
24 macies to participants or beneficiaries
25 in such plan; and

1 “(III) a list of all drugs dis-
2 pensed by such pharmacies to partici-
3 pants or beneficiaries enrolled in such
4 plan, and, with respect to each drug
5 dispensed—

6 “(aa) the amount charged,
7 per dosage unit, per 30-day sup-
8 ply, or per 90-day supply (as ap-
9 plicable) to the plan, and to par-
10 ticipants and beneficiaries;

11 “(bb) the median amount
12 charged to such plan, and the
13 interquartile range of the costs,
14 per dosage unit, per 30-day sup-
15 ply, and per 90-day supply, in-
16 cluding amounts paid by the par-
17 ticipants and beneficiaries, when
18 the same drug is dispensed by
19 other pharmacies that are not af-
20 filiated with or under common
21 ownership with the entity and
22 that are included in the phar-
23 macy network of such plan;

24 “(cc) the lowest cost per
25 dosage unit, per 30-day supply

1 and per 90-day supply, for each
2 such drug, including amounts
3 charged to the plan and to par-
4 ticipants and beneficiaries, that
5 is available from any pharmacy
6 included in the network of such
7 plan; and

8 “(dd) the net acquisition
9 cost per dosage unit, per 30-day
10 supply, and per 90-day supply, if
11 such drug is subject to a max-
12 imum price discount; and

13 “(B) with respect to any group health
14 plan, regardless of whether the plan is offered
15 by a specified large employer or whether it is a
16 specified large plan—

17 “(i) a summary document for the
18 group health plan that includes such infor-
19 mation described in clauses (i) through (iv)
20 of subparagraph (A), as specified by the
21 Secretary through guidance, program in-
22 struction, or otherwise (with no require-
23 ment of notice and comment rulemaking),
24 that the Secretary determines useful to
25 group health plans for purposes of select-

1 ing pharmacy benefit management serv-
2 ices, such as an estimated net price to
3 group health plan and participant or bene-
4 ficiary, a cost per claim, the fee structure
5 or reimbursement model, and estimated
6 cost per participant or beneficiary;

7 “(ii) a summary document for plans
8 to provide to participants and beneficiaries,
9 which shall be made available to partici-
10 pants or beneficiaries upon request to their
11 group health plan, that—

12 “(I) contains such information
13 described in clauses (iii), (iv), (v), and
14 (vi), as applicable, as specified by the
15 Secretary through guidance, program
16 instruction, or otherwise (with no re-
17 quirement of notice and comment
18 rulemaking) that the Secretary deter-
19 mines useful to participants or bene-
20 ficiaries in better understanding the
21 plan or benefits under such plan;

22 “(II) contains only aggregate in-
23 formation; and

24 “(III) states that participants
25 and beneficiaries may request specific,

1 claims-level information required to be
2 furnished under subsection (c) from
3 the group health plan; and

4 “(iii) with respect to drugs covered by
5 such plan during such reporting period—

6 “(I) the total net spending by the
7 plan for all such drugs;

8 “(II) the total amount received,
9 or expected to be received, by the plan
10 from any applicable entity in rebates,
11 fees, alternative discounts, or other
12 remuneration; and

13 “(III) to the extent feasible, in-
14 formation on the total amount of re-
15 muneration for such drugs, including
16 copayment assistance dollars paid, co-
17 payment cards applied, or other dis-
18 counts provided by each drug manu-
19 facturer (or entity administering co-
20 payment assistance on behalf of such
21 drug manufacturer) to participants
22 and beneficiaries;

23 “(iv) amounts paid directly or indi-
24 rectly in rebates, fees, or any other type of
25 compensation (as defined in section

1 408(b)(2)(B)(ii)(dd)(AA) of the Employee
2 Retirement Income Security Act (29
3 U.S.C. 1108(b)(2)(B)(ii)(dd)(AA))) to bro-
4 kerage firms, brokers, consultants, advi-
5 sors, or any other individual or firm, for—

6 “(I) the referral of the group
7 health plan’s business to an entity
8 providing pharmacy benefit manage-
9 ment services, including the identity
10 of the recipient of such amounts;

11 “(II) consideration of the entity
12 providing pharmacy benefit manage-
13 ment services by the group health
14 plan; or

15 “(III) the retention of the entity
16 by the group health plan;

17 “(v) an explanation of any benefit de-
18 sign parameters that encourage or require
19 participants and beneficiaries in such plan
20 to fill prescriptions at mail order, specialty,
21 or retail pharmacies that are affiliated with
22 or under common ownership with the enti-
23 ty providing pharmacy benefit management
24 services under such plan, including manda-
25 tory mail and specialty home delivery pro-

grams, retail and mail auto-refill programs, and cost-sharing assistance incentives directly or indirectly funded by such entity; and

“(vi) total gross spending on all drugs under the plan during the reporting period.

“(3) OPT-IN FOR GROUP HEALTH INSURANCE COVERAGE OFFERED BY A SPECIFIED LARGE EMPLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In the case of group health insurance coverage offered in connection with a group health plan that is offered by a specified large employer or is a specified large plan, such group health plan may, on an annual basis, for plan years beginning on or after the date that is 30 months after the date of enactment of this section, elect to require an entity providing pharmacy benefit management services on behalf of the health insurance issuer to submit to such group health plan a report that includes all of the information described in paragraph (2)(A), in addition to the information described in paragraph (2)(B).

“(4) PRIVACY REQUIREMENTS.—

“(A) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan shall report infor-

1 mation under paragraph (1) in a manner con-
2 sistent with the privacy regulations promul-
3 gated under section 13402(a) of the Health In-
4 formation Technology for Economic and Clin-
5 ical Health Act (42 U.S.C. 17932(a)) and con-
6 sistent with the privacy regulations promul-
7 gated under the Health Insurance Portability
8 and Accountability Act of 1996 in part 160 and
9 subparts A and E of part 164 of title 45, Code
10 of Federal Regulations (or successor regula-
11 tions) (referred to in this paragraph as the
12 ‘HIPAA privacy regulations’) and shall restrict
13 the use and disclosure of such information ac-
14 cording to such privacy regulations and such
15 HIPAA privacy regulations.

16 “(B) ADDITIONAL REQUIREMENTS.—

17 “(i) IN GENERAL.—An entity pro-
18 viding pharmacy benefit management serv-
19 ices on behalf of a group health plan that
20 submits a report under paragraph (1) shall
21 ensure that such report contains only sum-
22 mary health information, as defined in sec-
23 tion 164.504(a) of title 45, Code of Fed-
24 eral Regulations (or successor regulations).

1 “(ii) RESTRICTIONS.—In carrying out
2 this subsection, a group health plan shall
3 comply with section 164.504(f) of title 45,
4 Code of Federal Regulations (or a suc-
5 cessor regulation), and a plan sponsor shall
6 act in accordance with the terms of the
7 agreement described in such section.

8 “(C) RULE OF CONSTRUCTION.—

9 “(i) Nothing in this section shall be
10 construed to modify the requirements for
11 the creation, receipt, maintenance, or
12 transmission of protected health informa-
13 tion under the HIPAA privacy regulations.

14 “(ii) Nothing in this section shall be
15 construed to affect the application of any
16 Federal or State privacy or civil rights law,
17 including the HIPAA privacy regulations,
18 the Genetic Information Nondiscrimination
19 Act of 2008 (Public Law 110–233) (in-
20 cluding the amendments made by such
21 Act), the Americans with Disabilities Act
22 of 1990 (42 U.S.C. 12101 et seq.), section
23 504 of the Rehabilitation Act of 1973 (29
24 U.S.C. 794), section 1557 of the Patient
25 Protection and Affordable Care Act (42

1 U.S.C. 18116), title VI of the Civil Rights
2 Act of 1964 (42 U.S.C. 2000d), and title
3 VII of the Civil Rights Act of 1964 (42
4 U.S.C. 2000e).

5 “(D) WRITTEN NOTICE.—Each plan year,
6 group health plans shall provide to each partici-
7 pant or beneficiary written notice informing the
8 participant or beneficiary of the requirement for
9 entities providing pharmacy benefit manage-
10 ment services on behalf of the group health
11 plan to submit reports to group health plans
12 under paragraph (1), as applicable, which may
13 include incorporating such notification in plan
14 documents provided to the participant or bene-
15 ficiary, or providing individual notification.

16 “(E) LIMITATION TO BUSINESS ASSOCI-
17 ATES.—A group health plan receiving a report
18 under paragraph (1) may disclose such informa-
19 tion only to the entity from which the report
20 was received or to that entity’s business associ-
21 ates as defined in section 160.103 of title 45,
22 Code of Federal Regulations (or successor regu-
23 lations) or as permitted by the HIPAA privacy
24 regulations.

1 “(F) CLARIFICATION REGARDING PUBLIC
2 DISCLOSURE OF INFORMATION.—Nothing in
3 this section shall prevent an entity providing
4 pharmacy benefit management services on be-
5 half of a group health plan, from placing rea-
6 sonable restrictions on the public disclosure of
7 the information contained in a report described
8 in paragraph (1), except that such plan or enti-
9 ty may not—

10 “(i) restrict disclosure of such report
11 to the Department of Health and Human
12 Services, the Department of Labor, or the
13 Department of the Treasury; or

14 “(ii) prevent disclosure for the pur-
15 poses of subsection (c), or any other public
16 disclosure requirement under this section.

17 “(G) LIMITED FORM OF REPORT.—The
18 Secretary shall define through rulemaking a
19 limited form of the report under paragraph (1)
20 required with respect to any group health plan
21 established by a plan sponsor that is, or is af-
22 filiated with, a drug manufacturer, drug whole-
23 saler, or other direct participant in the drug
24 supply chain, in order to prevent anti-competi-
25 tive behavior.

1 “(5) STANDARD FORMAT AND REGULATIONS.—

2 “(A) IN GENERAL.—Not later than 18
3 months after the date of enactment of this sec-
4 tion, the Secretary shall specify through rule-
5 making a standard format for entities providing
6 pharmacy benefit management services on be-
7 half of group health plans, to submit reports re-
8 quired under paragraph (1).

9 “(B) ADDITIONAL REGULATIONS.—Not
10 later than 18 months after the date of enact-
11 ment of this section, the Secretary shall,
12 through rulemaking, promulgate any other final
13 regulations necessary to implement the require-
14 ments of this section. In promulgating such
15 regulations, the Secretary shall, to the extent
16 practicable, align the reporting requirements
17 under this section with the reporting require-
18 ments under section 9825.

19 “(c) REQUIREMENT TO PROVIDE INFORMATION TO
20 PARTICIPANTS OR BENEFICIARIES.—A group health plan,
21 upon request of a participant or beneficiary, shall provide
22 to such participant or beneficiary—

23 “(1) the summary document described in sub-
24 section (b)(2)(B)(ii); and

1 “(2) the information described in subsection
 2 (b)(2)(A)(i)(III) with respect to a claim made by or
 3 on behalf of such participant or beneficiary.

4 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
 5 tion shall be construed to permit a health insurance issuer,
 6 group health plan, entity providing pharmacy benefit man-
 7 agement services on behalf of a group health plan or
 8 health insurance issuer, or other entity to restrict disclo-
 9 sure to, or otherwise limit the access of, the Secretary to
 10 a report described in subsection (b)(1) or information re-
 11 lated to compliance with subsections (a), (b), or (c) of this
 12 section or section 4980D(g) by such issuer, plan, or entity.

13 “(e) DEFINITIONS.—In this section:

14 “(1) APPLICABLE ENTITY.—The term ‘applica-
 15 ble entity’ means—

16 “(A) an applicable group purchasing orga-
 17 nization, drug manufacturer, distributor, whole-
 18 saler, rebate aggregator (or other purchasing
 19 entity designed to aggregate rebates), or associ-
 20 ated third party;

21 “(B) any subsidiary, parent, affiliate, or
 22 subcontractor of a group health plan, health in-
 23 surance issuer, entity that provides pharmacy
 24 benefit management services on behalf of such

1 a plan or issuer, or any entity described in sub-
2 paragraph (A); or

3 “(C) such other entity as the Secretary
4 may specify through rulemaking.

5 “(2) APPLICABLE GROUP PURCHASING ORGANI-
6 ZATION.—The term ‘applicable group purchasing or-
7 ganization’ means a group purchasing organization
8 that is affiliated with or under common ownership
9 with an entity providing pharmacy benefit manage-
10 ment services.

11 “(3) CONTRACTED COMPENSATION.—The term
12 ‘contracted compensation’ means the sum of any in-
13 gredient cost and dispensing fee for a drug (inclusive
14 of the out-of-pocket costs to the participant or bene-
15 ficiary), or another analogous compensation struc-
16 ture that the Secretary may specify through regula-
17 tions.

18 “(4) GROSS SPENDING.—The term ‘gross
19 spending’, with respect to prescription drug benefits
20 under a group health plan, means the amount spent
21 by a group health plan on prescription drug benefits,
22 calculated before the application of rebates, fees, al-
23 ternative discounts, or other remuneration.

24 “(5) NET SPENDING.—The term ‘net spending’,
25 with respect to prescription drug benefits under a

1 group health plan, means the amount spent by a
2 group health plan on prescription drug benefits, cal-
3 culated after the application of rebates, fees, alter-
4 native discounts, or other remuneration.

5 “(6) PLAN SPONSOR.—The term ‘plan sponsor’
6 has the meaning given such term in section 3(16)(B)
7 of the Employee Retirement Income Security Act of
8 1974 (29 U.S.C. 1002(16)(B)).

9 “(7) REMUNERATION.—The term ‘remunera-
10 tion’ has the meaning given such term by the Sec-
11 retary, through rulemaking, which shall be reeval-
12 ated by the Secretary every 5 years.

13 “(8) SPECIFIED LARGE EMPLOYER.—The term
14 ‘specified large employer’ means, in connection with
15 a group health plan established or maintained by a
16 single employer, with respect to a calendar year or
17 a plan year, as applicable, an employer who em-
18 ployed an average of at least 100 employees on busi-
19 ness days during the preceding calendar year or plan
20 year and who employs at least 1 employee on the
21 first day of the calendar year or plan year.

22 “(9) SPECIFIED LARGE PLAN.—The term ‘spec-
23 ified large plan’ means a group health plan estab-
24 lished or maintained by a plan sponsor described in
25 clause (ii) or (iii) of section 3(16)(B) of the Em-

1 ployee Retirement Income Security Act of 1974 (29
 2 U.S.C. 1002(16)(B)) that had an average of at least
 3 100 participants on business days during the pre-
 4 ceding calendar year or plan year, as applicable.

5 “(10) WHOLESALE ACQUISITION COST.—The
 6 term ‘wholesale acquisition cost’ has the meaning
 7 given such term in section 1847A(c)(6)(B) of the
 8 Social Security Act (42 U.S.C. 1395w–
 9 3a(c)(6)(B)).”;

10 (2) EXCEPTION FOR CERTAIN GROUP HEALTH
 11 PLANS.—Section 9831(a)(2) of the Internal Revenue
 12 Code of 1986 is amended by inserting “other than
 13 with respect to section 9826,” before “any group
 14 health plan”.

15 (3) ENFORCEMENT.—Section 4980D of the In-
 16 ternal Revenue Code of 1986 is amended by adding
 17 at the end the following new subsection:

18 “(g) APPLICATION TO REQUIREMENTS IMPOSED ON
 19 CERTAIN ENTITIES PROVIDING PHARMACY BENEFIT
 20 MANAGEMENT SERVICES.—In the case of any requirement
 21 under section 9826 that applies with respect to an entity
 22 providing pharmacy benefit management services on be-
 23 half of a group health plan, any reference in this section
 24 to such group health plan (and the reference in subsection

1 (e)(1) to the employer) shall be treated as including a ref-
 2 erence to such entity.”.

3 (4) CLERICAL AMENDMENT.—The table of sec-
 4 tions for subchapter B of chapter 100 of the Inter-
 5 nal Revenue Code of 1986 is amended by adding at
 6 the end the following new item:

“Sec. 9826. Oversight of entities that provide pharmacy benefit management
 services.”.

7 **SEC. 902. FULL REBATE PASS THROUGH TO PLAN; EXCEP-**
 8 **TION FOR INNOCENT PLAN FIDUCIARIES.**

9 (a) IN GENERAL.—Section 408(b)(2) of the Em-
 10 ployee Retirement Income Security Act of 1974 (29
 11 U.S.C. 1108(b)(2)) is amended—

12 (1) in subparagraph (B)(viii)—

13 (A) by redesignating subclauses (II)
 14 through (IV) as subclauses (III) through (V),
 15 respectively;

16 (B) in subclause (I)—

17 (i) by striking “subclause (II)” and
 18 inserting “subclause (III)”; and

19 (ii) by striking “subclauses (II) and
 20 (III)” and inserting “subclauses (III) and
 21 (IV)”; and

22 (C) by inserting after subclause (I) the fol-
 23 lowing:

1 “(II) 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 to remit required amounts
5 under subparagraph (C)(i), if the following condi-
6 tions are met:

7 “(aa) The responsible plan fiduciary did
8 not know that the covered service provider
9 failed or would fail to make required remit-
10 tances and reasonably believed that the covered
11 service provider remitted such required
12 amounts.

13 “(bb) The responsible plan fiduciary, upon
14 discovering that the covered service provider
15 failed to remit the required amounts, requests
16 in writing that the covered service provider
17 remit such amounts.

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

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

1 “(C)(i)(I) For plan years beginning on or after
2 the date that is 30 months after the date of enact-
3 ment of this subparagraph (referred to in this clause
4 as the ‘effective date’), no contract or arrangement
5 or renewal or extension of a contract or arrange-
6 ment, entered into on or after the effective date, for
7 services between a covered plan and a covered serv-
8 ice provider, through a health insurance issuer offer-
9 ing group health insurance coverage, a third-party
10 administrator, an entity providing pharmacy benefit
11 management services, or other entity, for pharmacy
12 benefit management services, is reasonable within
13 the meaning of this paragraph unless such entity
14 providing pharmacy benefit management services—

15 “(aa) remits 100 percent of rebates, fees,
16 alternative discounts, and other remuneration
17 received from any applicable entity that are re-
18 lated to utilization of drugs or drug spending
19 under such health plan or health insurance cov-
20 erage, to the group health plan or health insur-
21 ance issuer offering group health insurance cov-
22 erage; and

23 “(bb) does not enter into any contract for
24 pharmacy benefit management services on be-
25 half of such a plan or coverage, with an applica-

1 ble entity unless 100 percent of rebates, fees,
 2 alternative discounts, and other remuneration
 3 received under such contract that are related to
 4 the utilization of drugs or drug spending under
 5 such group health plan or health insurance cov-
 6 erage are remitted to the group health plan or
 7 health insurance issuer by the entity providing
 8 pharmacy benefit management services.

9 “(II) Nothing in subclause (I) shall be con-
 10 strued to affect the term of a contract or arrange-
 11 ment, as in effect on the effective date (as described
 12 in such subclause), except that such subclause shall
 13 apply to any renewal or extension of such a contract
 14 or arrangement entered into on or after such effec-
 15 tive date, as so described.

16 “(ii) With respect to such rebates, fees, alter-
 17 native discounts, and other remuneration—

18 “(I) the rebates, fees, alternative dis-
 19 counts, and other remuneration under clause
 20 (i)(I) shall be—

21 “(aa) remitted—

22 “(AA) on a quarterly basis, to
 23 the group health plan or the group
 24 health insurance issuer, not later than

1 90 days after the end of each quarter;
2 or

3 “(BB) in the case of an under-
4 payment in a remittance for a prior
5 quarter, as soon as practicable, but
6 not later than 90 days after notice of
7 the underpayment is first given;

8 “(bb) fully disclosed and enumerated
9 to the group health plan or health insur-
10 ance issuer; and

11 “(cc) returned to the covered service
12 provider for pharmacy benefit management
13 services on behalf of the group health plan
14 if any audit by a plan sponsor, issuer or a
15 third party designated by a plan sponsor,
16 indicates that the amounts received are in-
17 correct after such amounts have been paid
18 to the group health plan or health insur-
19 ance issuer;

20 “(II) the Secretary may establish proce-
21 dures for the remittance of rebates fees, alter-
22 native discounts, and other remuneration under
23 subclause (I)(aa) and the disclosure of rebates,
24 fees, alternative discounts, and other remunera-
25 tion under subclause (I)(bb); and

1 “(III) the records of such rebates, fees, al-
2 ternative discounts, and other remuneration
3 shall be available for audit by the plan sponsor,
4 issuer, or a third party designated by a plan
5 sponsor, not less than once per plan year.

6 “(iii) To ensure that an entity providing phar-
7 macy benefit management services is able to meet
8 the requirements of clause (ii)(I), a rebate
9 aggregator (or other purchasing entity designed to
10 aggregate rebates) and an applicable group pur-
11 chasing organization shall remit such rebates to the
12 entity providing pharmacy benefit management serv-
13 ices not later than 45 days after the end of each
14 quarter.

15 “(iv) A third-party administrator of a group
16 health plan, a health insurance issuer offering group
17 health insurance coverage, or a covered service pro-
18 vider for pharmacy benefit management services
19 under such health plan or health insurance coverage
20 shall make rebate contracts with rebate aggregators
21 or drug manufacturers available for audit by such
22 plan sponsor or designated third party, subject to
23 reasonable restrictions (as determined by the Sec-
24 retary) on confidentiality to prevent re-disclosure of

1 such contracts or use of such information in audits
2 for purposes unrelated to this section.

3 “(v) Audits carried out under clauses (ii)(III)
4 and (iv) shall be performed by an auditor selected by
5 the responsible plan fiduciary. Payment for such au-
6 dits shall not be made, whether directly or indirectly,
7 by the entity providing pharmacy benefit manage-
8 ment services.

9 “(vi) Nothing in this subparagraph shall be
10 construed to—

11 “(I) prohibit reasonable payments to enti-
12 ties offering pharmacy benefit management
13 services for bona fide services using a fee struc-
14 ture not described in this subparagraph, pro-
15 vided that such fees are transparent and quan-
16 tifiable to group health plans and health insur-
17 ance issuers;

18 “(II) require a third-party administrator of
19 a group health plan or covered service provider
20 for pharmacy benefit management services
21 under such health plan or health insurance cov-
22 erage to remit bona fide service fees to the
23 group health plan;

24 “(III) limit the ability of a group health
25 plan or health insurance issuer to pass through

1 rebates, fees, alternative discounts, and other
2 remuneration to the participant or beneficiary;
3 or

4 “(IV) modify the requirements for the cre-
5 ation, receipt, maintenance, or transmission of
6 protected health information under the privacy
7 regulations promulgated under the Health In-
8 surance Portability and Accountability Act of
9 1996 in part 160 and subparts A and E of part
10 164 of title 45, Code of Federal Regulations (or
11 successor regulations).

12 “(vii) For purposes of this subparagraph—

13 “(I) the terms ‘applicable entity’ and ‘ap-
14 plicable group purchasing organization’ have
15 the meanings given such terms in section
16 726(e);

17 “(II) the terms ‘covered plan’, ‘covered
18 service provider’, and ‘responsible plan fidu-
19 ciary’ have the meanings given such terms in
20 subparagraph (B); and

21 “(III) the terms ‘group health insurance
22 coverage’, ‘health insurance coverage’, and
23 ‘health insurance issuer’ have the meanings
24 given such terms in section 733.”.

1 (b) RULE OF CONSTRUCTION.—Subclause (II)(aa) of
 2 section 408(b)(2)(B)(viii) of the Employee Retirement In-
 3 come Security Act of 1974 (29 U.S.C.
 4 1108(b)(2)(B)(viii)), as amended by subsection (a), shall
 5 not be construed to relieve or limit a responsible plan fidu-
 6 ciary from the duty to monitor the practices of any covered
 7 service provider that contracts with the applicable covered
 8 plan, including for the purposes of ensuring the reason-
 9 ableness of compensation. For purposes of this subsection,
 10 the terms “covered plan”, “covered service provider”, and
 11 “responsible plan fiduciary” have the meanings given such
 12 terms in section 408(b)(2)(B)(ii) of the Employee Retire-
 13 ment Income Security Act of 1974 (29 U.S.C.
 14 1108(b)(2)(B)(ii)).

15 (c) CLARIFICATION OF COVERED SERVICE PRO-
 16 VIDER.—

17 (1) SERVICES.—

18 (A) IN GENERAL.—Section
 19 408(b)(2)(B)(ii)(I)(bb) of the Employee Retire-
 20 ment Income Security Act of 1974 (29 U.S.C.
 21 1108(b)(2)(B)(ii)(I)(bb)) is amended—

22 (i) in subitem (AA) by striking “Bro-
 23 kerage services,” and inserting “Services
 24 (including brokerage services),”; and

25 (ii) in subitem (BB)—

1 (I) by striking “Consulting,” and
2 inserting “Other services,”; and

3 (II) by striking “related to the
4 development or implementation of
5 plan design” and all that follows
6 through the period at the end and in-
7 serting “including any of the fol-
8 lowing: plan design, insurance or in-
9 surance product selection (including
10 vision and dental), recordkeeping,
11 medical management, benefits admin-
12 istration selection (including vision
13 and dental), stop-loss insurance, phar-
14 macy benefit management services,
15 wellness design and management serv-
16 ices, transparency tools, group pur-
17 chasing organization agreements and
18 services, participation in and services
19 from preferred vendor panels, disease
20 management, compliance services, em-
21 ployee assistance programs, or third-
22 party administration services, or con-
23 sulting services related to any such
24 services.”.

1 (B) SENSE OF CONGRESS.—It is the sense
 2 of Congress that the amendment made by sub-
 3 paragraph (A) clarifies the existing requirement
 4 of covered service providers with respect to
 5 services described in section
 6 408(b)(2)(B)(ii)(I)(bb)(BB) of the Employee
 7 Retirement Income Security Act of 1974 (29
 8 U.S.C. 1108(b)(2)(B)(ii)(I)(bb)(BB)) that were
 9 in effect since the application date described in
 10 section 202(e) of the No Surprises Act (Public
 11 Law 116–260; 29 U.S.C. 1108 note), and does
 12 not impose any additional requirement under
 13 section 408(b)(2)(B) of such Act.

14 (2) CERTAIN ARRANGEMENTS FOR PHARMACY
 15 BENEFIT MANAGEMENT SERVICES CONSIDERED AS
 16 INDIRECT.—

17 (A) IN GENERAL.—Section 408(b)(2)(B)(i)
 18 of the Employee Retirement Income Security
 19 Act of 1974 (29 U.S.C. 1108(b)(2)(B)(i)) is
 20 amended—

21 (i) by striking “requirements of this
 22 clause” and inserting “requirements of this
 23 subparagraph”; and

24 (ii) by adding at the end the fol-
 25 lowing: “For purposes of applying section

1 406(a)(1)(C) with respect to a transaction
 2 described under this subparagraph or sub-
 3 paragraph (C), a contract or arrangement
 4 for services between a covered plan and an
 5 entity providing services to the plan, in-
 6 cluding a health insurance issuer providing
 7 health insurance coverage in connection
 8 with the covered plan, in which such entity
 9 contracts, in connection with such plan,
 10 with a service provider for pharmacy ben-
 11 efit management services, shall be consid-
 12 ered an indirect furnishing of goods, serv-
 13 ices, or facilities between the covered plan
 14 and the service provider for pharmacy ben-
 15 efit management services acting as the
 16 party in interest.”.

17 (B) HEALTH INSURANCE ISSUER AND
 18 HEALTH INSURANCE COVERAGE DEFINED.—
 19 Section 408(b)(2)(B)(ii)(I)(aa) of such Act (29
 20 U.S.C. 1108(b)(2)(B)(ii)(I)(aa)) is amended by
 21 inserting before the period at the end “and the
 22 terms ‘health insurance coverage’ and ‘health
 23 insurance issuer’ have the meanings given such
 24 terms in section 733(b)”.

1 (C) TECHNICAL AMENDMENT.—Section
2 408(b)(2)(B)(ii)(I)(aa) of the Employee Retirement
3 Income Security Act of 1974 (29 U.S.C.
4 1108(b)(2)(B)(ii)(I)(aa)) is amended by inserting
5 “in” after “defined”.

6 **SEC. 903. INCREASING TRANSPARENCY IN GENERIC DRUG**
7 **APPLICATIONS.**

8 (a) IN GENERAL.—Section 505(j)(3) of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)) is
10 amended by adding at the end the following:

11 “(H)(i) Upon request (in controlled correspondence
12 or an analogous process) by a person that has submitted
13 or intends to submit an abbreviated application under this
14 subsection for a drug that is required by regulation to contain
15 one or more of the same inactive ingredients in the
16 same concentrations as the listed drug referred to, or for
17 which the Secretary determines there is a scientific justification
18 for an approach that is in vitro, in whole or in
19 part, to be used to demonstrate bioequivalence for a drug
20 if such a drug contains one or more of the same inactive
21 ingredients in the same concentrations as the listed drug
22 referred to, the Secretary shall inform the person whether
23 such drug is qualitatively and quantitatively the same as
24 the listed drug. The Secretary may also provide such information
25 to such a person on the Secretary’s own initiative

1 during the review of an abbreviated application under this
2 subsection for such drug.

3 “(ii) Notwithstanding section 301(j), if the Secretary
4 determines that such drug is not qualitatively or quan-
5 titatively the same as the listed drug, the Secretary shall
6 identify and disclose to the person—

7 “(I) the ingredient or ingredients that cause
8 such drug not to be qualitatively or quantitatively
9 the same as the listed drug; and

10 “(II) for any ingredient for which there is an
11 identified quantitative deviation, the amount of such
12 deviation.

13 “(iii) If the Secretary determines that such drug is
14 qualitatively and quantitatively the same as the listed
15 drug, the Secretary shall not change or rescind such deter-
16 mination after the submission of an abbreviated applica-
17 tion for such drug under this subsection unless—

18 “(I) the formulation of the listed drug has been
19 changed and the Secretary has determined that the
20 prior listed drug formulation was withdrawn for rea-
21 sons of safety or effectiveness; or

22 “(II) the Secretary makes a written determina-
23 tion that the prior determination must be changed
24 because an error has been identified.

1 “(iv) If the Secretary makes a written determination
2 described in clause (iii)(II), the Secretary shall provide no-
3 tice and a copy of the written determination to the person
4 making the request under clause (i).

5 “(v) The disclosures authorized under clauses (i) and
6 (ii) are disclosures authorized by law, including for pur-
7 poses of section 1905 of title 18, United States Code. This
8 subparagraph shall not otherwise be construed to author-
9 ize the disclosure of nonpublic qualitative or quantitative
10 information about the ingredients in a listed drug, or to
11 affect the status, if any, of such information as trade se-
12 cret or confidential commercial information for purposes
13 of section 301(j) of this Act, section 552 of title 5, United
14 States Code, or section 1905 of title 18, United States
15 Code.”.

16 (b) GUIDANCE.—

17 (1) IN GENERAL.—Not later than one year
18 after the date of enactment of this Act, the Sec-
19 retary of Health and Human Services shall issue
20 draft guidance, or update guidance, describing how
21 the Secretary will determine whether a drug is quali-
22 tatively and quantitatively the same as the listed
23 drug (as such terms are used in section
24 505(j)(3)(H) of the Federal Food, Drug, and Cos-

1 metec Act, as added by subsection (a)), including
2 with respect to assessing pH adjusters.

3 (2) PROCESS.—In issuing guidance under this
4 subsection, the Secretary of Health and Human
5 Services shall—

6 (A) publish draft guidance;

7 (B) provide a period of at least 60 days for
8 comment on the draft guidance; and

9 (C) after considering any comments re-
10 ceived and not later than one year after the
11 close of the comment period on the draft guid-
12 ance, publish final guidance.

13 (c) APPLICABILITY.—Section 505(j)(3)(H) of the
14 Federal Food, Drug, and Cosmetic Act, as added by sub-
15 section (a), applies beginning on the date of enactment
16 of this Act, irrespective of the date on which the guidance
17 required by subsection (b) is finalized.

18 **SEC. 904. TITLE 35 AMENDMENTS.**

19 (a) IN GENERAL.—Section 271(e) of title 35, United
20 States Code, is amended—

21 (1) in paragraph (2)(C), in the flush text fol-
22 lowing clause (ii), by adding at the end the fol-
23 lowing: “With respect to a submission described in
24 clause (ii), the act of infringement shall extend to
25 any patent that claims the biological product, a

1 method of using the biological product, or a method
2 or product used to manufacture the biological prod-
3 uct.”; and

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

5 “(7)(A) Subject to subparagraphs (C), (D), and (E),
6 if the sponsor of an approved application for a reference
7 product, as defined in section 351(i) of the Public Health
8 Service Act (42 U.S.C. 262(i)) (referred to in this para-
9 graph as the ‘reference product sponsor’), brings an action
10 for infringement under this section against an applicant
11 for approval of a biological product under section 351(k)
12 of such Act that references that reference product (re-
13 ferred to in this paragraph as the ‘subsection (k) appli-
14 cant’), the reference product sponsor may assert in the
15 action a total of not more than 20 patents of the type
16 described in subparagraph (B), not more than 10 of which
17 shall have issued after the date specified in section
18 351(l)(7)(A) of such Act.

19 “(B) The patents described in this subparagraph are
20 patents that satisfy each of the following requirements:

21 “(i) Patents that claim the biological product
22 that is the subject of an application under section
23 351(k) of the Public Health Service Act (42 U.S.C.
24 262(k)) (or a use of that product) or a method or

1 product used in the manufacture of such biological
2 product.

3 “(ii) Patents that are included on the list of
4 patents described in paragraph (3)(A) of section
5 351(l) of the Public Health Service Act (42 U.S.C.
6 262(l)), including as provided under paragraph (7)
7 of such section 351(l).

8 “(iii) Patents that—

9 “(I) have an actual filing date of more
10 than 4 years after the date on which the ref-
11 erence product is approved; or

12 “(II) include a claim to a method in a
13 manufacturing process that is not used by the
14 reference product sponsor.

15 “(C) The court in which an action described in sub-
16 paragraph (A) is brought may increase the number of pat-
17 ents limited under that subparagraph—

18 “(i) if the request to increase that number is
19 made without undue delay; and

20 “(ii)(I) if the interest of justice so requires; or

21 “(II) for good cause shown, which—

22 “(aa) shall be established if the subsection
23 (k) applicant fails to provide information re-
24 quired section 351(k)(2)(A) of the Public
25 Health Service Act (42 U.S.C. 262(k)(2)(A))

1 that would enable the reference product sponsor
2 to form a reasonable belief with respect to
3 whether a claim of infringement under this sec-
4 tion could reasonably be asserted; and

5 “(bb) may be established—

6 “(AA) if there is a material change to
7 the biological product (or process with re-
8 spect to the biological product) of the sub-
9 section (k) applicant that is the subject of
10 the application;

11 “(BB) if, with respect to a patent on
12 the supplemental list described in section
13 351(l)(7)(A) of Public Health Service Act
14 (42 U.S.C. 262(l)(7)(A)), the patent would
15 have issued before the date specified in
16 such section 351(l)(7)(A) but for the fail-
17 ure of the Office to issue the patent or a
18 delay in the issuance of the patent, as de-
19 scribed in paragraph (1) of section 154(b)
20 and subject to the limitations under para-
21 graph (2) of such section 154(b); or

22 “(CC) for another reason that shows
23 good cause, as determined appropriate by
24 the court.

1 “(D) In determining whether good cause has been
2 shown for the purposes of subparagraph (C)(ii)(II), a
3 court may consider whether the reference product sponsor
4 has provided a reasonable description of the identity and
5 relevance of any information beyond the subsection (k) ap-
6 plication that the court believes is necessary to enable the
7 court to form a belief with respect to whether a claim of
8 infringement under this section could reasonably be as-
9 serted.

10 “(E) The limitation imposed under subparagraph
11 (A)—

12 “(i) shall apply only if the subsection (k) appli-
13 cant completes all actions required under paragraphs
14 (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of
15 section 351(l) of the Public Health Service Act (42
16 U.S.C. 262(l)); and

17 “(ii) shall not apply with respect to any patent
18 that claims, with respect to a biological product, a
19 method for using that product in therapy, diagnosis,
20 or prophylaxis, such as an indication or method of
21 treatment or other condition of use.”.

22 (b) APPLICABILITY.—The amendments made by sub-
23 section (a) shall apply with respect to an application sub-
24 mitted under section 351(k) of the Public Health Service

1 Act (42 U.S.C. 262(k)) on or after the date of enactment
 2 of this Act.

3 **TITLE X—MISCELLANEOUS**

4 **SEC. 1001. EXTENSION OF SAFE HARBOR FOR ABSENCE OF** 5 **DEDUCTIBLE FOR TELEHEALTH.**

6 Section 223(c)(2)(E)(ii) of the Internal Revenue
 7 Code of 1986 is amended to read as follows:

8 “(ii) SAFE HARBOR FOR ABSENCE OF
 9 DEDUCTIBLE FOR TELEHEALTH.—

10 “(I) IN GENERAL.—In the case
 11 of an eligible month or an eligible
 12 plan year, a plan shall not fail to be
 13 treated as a high deductible health
 14 plan by reason of failing to have a de-
 15 ductible for telehealth and other re-
 16 mote care services.

17 “(II) ELIGIBLE MONTH.—For
 18 purposes of this clause, the term ‘eli-
 19 gible month’ means months beginning
 20 after March 31, 2022, and before
 21 January 1, 2023, and months begin-
 22 ning after March 31, 2025, and be-
 23 fore January 1, 2026.

24 “(III) ELIGIBLE PLAN YEAR.—
 25 For purposes of this clause, the term

1 ‘eligible plan year’ means plan years
2 beginning—

3 “(aa) on or before December
4 31, 2021,

5 “(bb) after December 31,
6 2022, and before January 1,
7 2025, or

8 “(cc) after December 31,
9 2024, and before January 1,
10 2027.”.

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