

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

Purpose: In the nature of a substitute.

**IN THE SENATE OF THE UNITED STATES—119th Cong., 1st Sess.**

**S. 891**

To extend expiring health provisions and improve health care delivery.

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

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended  
to be proposed by Mr. WYDEN (for himself and Mr.  
SANDERS)

Viz:

1 Strike all after the enacting clause and insert the fol-

2 lowing:

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

4 (a) SHORT TITLE.—This Act may be cited as the

5 “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.

## 2

- 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.

## 3

- 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.

## 4

- 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.

## 5

- 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-

essary for such State to provide payment to an eligible out-of-State provider under such State plan (or a waiver of such plan), such as the provider's name and National Provider Identifier (and such other information specified by the Secretary); and

“(ii) provides that an eligible out-of-State provider that enrolls as a participating provider in the State plan (or a waiver of such plan) through such process shall be so enrolled for a 5-year period, unless the provider is terminated or excluded from participation during such period.

“(B) DEFINITIONS.—In this paragraph:

“(i) **ELIGIBLE OUT-OF-STATE PROVIDER.**—The term ‘eligible out-of-State provider’ means, with respect to a State, a provider—

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

“(II) that—

“(aa) was determined by the Secretary to have a limited risk of fraud, waste, and abuse for 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;



1 “(bb) excluded from partici-  
2 pation in the State plan (or a  
3 waiver of such plan) pursuant to  
4 part 1002 of title 42, Code of  
5 Federal Regulations (or any suc-  
6 cessor regulation), or State law;  
7 or

8 “(cc) terminated from par-  
9 ticipating in a Federal health  
10 care program or the State plan  
11 (or a waiver of such plan) for a  
12 reason described in paragraph  
13 (8)(A).

14 “(ii) QUALIFYING INDIVIDUAL.—The  
15 term ‘qualifying individual’ means an indi-  
16 vidual under 21 years of age who is en-  
17 rolled under the State plan (or waiver of  
18 such plan).

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

22 (b) CONFORMING AMENDMENTS.—

23 (1) Section 1902(a)(77) of the Social Security  
24 Act (42 U.S.C. 1396a(a)(77)) is amended by insert-  
25 ing “enrollment,” after “screening,”.

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

(3) Section 2107(e)(1)(G) of such Act (42 U.S.C. 1397gg(e)(1)(G)) is amended by inserting “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

(II) by inserting “(including, with respect to such information provided 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-

1           tation services provided under this subsection  
2           on or after July 9, 2027, the State, not less fre-  
3           quently than annually, shall provide to the Sec-  
4           retary the same information regarding such  
5           services as the State is required to provide  
6           under subsection (c)(11)(B).”; and

7           (C) in subsection (k)(3)(E)—

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

10                   (ii) by inserting before the period, the  
11                   following: “, and with respect to home-  
12                   maker services, home health aide services,  
13                   personal care services, and habilitation  
14                   services provided under this subsection on  
15                   or after July 9, 2027, not less frequently  
16                   than annually, the same information re-  
17                   garding such services as the State is re-  
18                   quired to provide under subsection  
19                   (c)(11)(B)”.

20           (b) DEMONSTRATION PROGRAM TO EXPAND HCBS  
21           COVERAGE UNDER SECTION 1915(c) WAIVERS.—Section  
22           1915(c) of the Social Security Act (42 U.S.C. 1396n(c)),  
23           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.



1       1396d(v)(1)(A)) is amended by striking “, but less  
2       than 65,”.

3       (b) APPLICATION TO CERTAIN STATES.—A State  
4       that, as of the date of enactment of this Act, provides for  
5       making medical assistance available to individuals de-  
6       scribed in subclause (XV) or (XVI) of section  
7       1902(a)(10)(A)(ii) of the Social Security Act (42 U.S.C.  
8       1396a(a)(10)(A)(ii)) shall not be regarded as failing to  
9       comply with the requirements of either such subclause (as  
10      amended by subsection (a)(1)) or with section  
11      1905(v)(1)(A) of the Social Security Act (42 U.S.C.  
12      1396d(v)(1)(A)) (as amended by subsection (a)(2)) before  
13      January 1, 2027.

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

17      (a) IN GENERAL.—Section 1902 of the Social Secu-  
18      rity Act (42 U.S.C. 1396a) is amended—

19                      (1) in subsection (a)—

20                              (A) in paragraph (86), by striking “and”  
21                              at the end;

22                              (B) in paragraph (87), by striking the pe-  
23                              riod at the end and inserting “; and”; and

24                              (C) by inserting after paragraph (87), the  
25                              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)



1 of such section (as amended by this sec-  
2 tion); and

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

9 (B) NO RECOUPMENT OF PAYMENTS AL-  
10 READY MADE TO HOSPITALS.—A State shall not  
11 recoup any payment adjustment made by the  
12 State to a hospital for a Medicaid State plan  
13 rate year described in subparagraph (A) if such  
14 payment adjustment is consistent with section  
15 1923(g) of such Act (42 U.S.C. 1396r-4(g)) as  
16 in effect on October 1, 2021.

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

20 (i) IN GENERAL.—Subject to para-  
21 graph (2), solely for the purpose of allow-  
22 ing a State to increase the amount of a  
23 payment adjustment to a hospital for a  
24 Medicaid State plan rate year described in  
25 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

1 all cost information collected, whether a  
2 pharmacy is a retail community pharmacy  
3 or an applicable non-retail pharmacy, in-  
4 cluding whether such pharmacy is an affil-  
5 iate (as defined in subsection (k)(14)),  
6 and, in the case of an applicable non-retail  
7 pharmacy, which type of applicable non-re-  
8 tail pharmacy it is using the relevant phar-  
9 macy type indicators included in the guid-  
10 ance required by subsection (d)(2) of sec-  
11 tion 112 of the Bipartisan Health Care  
12 Act.”;

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

15 “(F) SURVEY REPORTING.—In order to  
16 meet the requirement of section 1902(a)(54), a  
17 State shall require that any retail community  
18 pharmacy or applicable non-retail pharmacy in  
19 the State that receives any payment, reimburse-  
20 ment, administrative fee, discount, rebate, or  
21 other price concession related to the dispensing  
22 of covered outpatient drugs to individuals re-  
23 ceiving benefits under this title, regardless of  
24 whether such payment, reimbursement, admin-  
25 istrative 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;

“(II) is passed through in its entirety (except as reduced under Federal or State laws and regulations in response to instances of waste, fraud, or abuse) by the entity or PBM to the pharmacy or provider that dispenses the drug; and

“(III) is made in a manner that  
is consistent with sections 447.502,  
447.512, 447.514, and 447.518 of  
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

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

4           “(14) PHARMACY BENEFIT MANAGER.—The  
5           term ‘pharmacy benefit manager’ means any person  
6           or entity that, either directly or through an inter-  
7           mediary, acts as a price negotiator or group pur-  
8           chaser on behalf of a State, managed care entity (as  
9           defined in section 1903(m)(9)(D)), or other specified  
10          entity (as so defined), or manages the prescription  
11          drug benefits provided by a State, managed care en-  
12          tity, or other specified entity, including the proc-  
13          essing and payment of claims for prescription drugs,  
14          the performance of drug utilization review, the proc-  
15          essing of drug prior authorization requests, the man-  
16          aging of appeals or grievances related to the pre-  
17          scription drug benefits, contracting with pharmacies,  
18          controlling the cost of covered outpatient drugs, or  
19          the provision of services related thereto. Such term  
20          includes any person or entity that acts as a price ne-  
21          gotiator (with regard to payment amounts to phar-  
22          macies and providers for a covered outpatient drug  
23          or the net cost of the drug) or group purchaser on  
24          behalf of a State, managed care entity, or other  
25          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

1           (3) by adding at the end the following new sub-  
2       paragraph:

3                   “(C) PAYMENT RULE FOR PORTION OF  
4       2025 AND 2026.—

5                   “(i) IN GENERAL.—A telehealth serv-  
6       ice furnished to an eligible telehealth indi-  
7       vidual by a Federally qualified health cen-  
8       ter or rural health clinic on or after April  
9       1, 2025, and before January 1, 2027, shall  
10      be paid as a Federally qualified health cen-  
11      ter service or rural health clinic service (as  
12      applicable) under the prospective payment  
13      system established under section 1834(o)  
14      or the methodology for all-inclusive rates  
15      established under section 1833(a)(3), re-  
16      spectively.

17                  “(ii) TREATMENT OF COSTS.—Costs  
18      associated with the furnishing of telehealth  
19      services by a Federally qualified health  
20      center or rural health clinic on or after  
21      April 1, 2025, and before January 1,  
22      2027, shall be considered allowable costs  
23      for purposes of the prospective payment  
24      system established under section 1834(o)  
25      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



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

6 (3) in subsection (b)—

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

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

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

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

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

17 “(c) SUBSEQUENT STUDY AND REPORT.—

18 “(1) IN GENERAL.—Not later than September  
19 30, 2028, the Secretary shall conduct a study to—

20 “(A) analyze, to the extent practicable, the  
21 criteria established by hospitals under the Acute  
22 Hospital Care at Home initiative to determine  
23 which individuals may be furnished services  
24 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 (1) in paragraph (1)(D)(ii), by striking “that  
2 does not exceed \$1 for” and all that follows through  
3 the period at the end and inserting “that does not  
4 exceed—

5 “(I) for a plan year before  
6 2027—

7 “(aa) for a generic drug or a  
8 preferred drug that is a multiple  
9 source drug (as defined in section  
10 1927(k)(7)(A)(i)), \$1 or, if less,  
11 the copayment amount applicable  
12 to an individual under clause  
13 (iii); and

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

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

20 “(aa) for a generic drug, \$0;

21 “(bb) for a preferred drug  
22 that is a multiple source drug (as  
23 defined in section  
24 1927(k)(7)(A)(i)), the dollar  
25 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

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

13 “(i) the amount of cost sharing that  
14 would apply if such provider had been par-  
15 ticipating in the network of such plan; or

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

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

23 “(i) notify enrollees of their cost-shar-  
24 ing protections under this paragraph and  
25 make such notifications, to the extent



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

5 “(ii) include information regarding  
6 such cost-sharing protections in the pro-  
7 vider directory of each specified MA plan  
8 offered by the MA organization.; and

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

12 (2) REQUIRED PROVIDER DIRECTORY ACCU-  
13 RACY ANALYSIS AND REPORTS.—

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

18 “(6) PROVIDER DIRECTORY ACCURACY ANAL-  
19 YSIS AND REPORTS.—

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

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

“(i) Conduct an analysis estimating the accuracy of the provider directory information of such plan using a random sample of providers included in such provider 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.

“(ii) Submit to the Secretary a report containing the results of the analysis conducted under clause (i), including an accuracy score for such provider directory information (as determined using a plan verification method specified by the Secretary 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

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

3 “(B) is—

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

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

12 “(C) the Secretary determines is—

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

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

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

24 (b) PAYMENT AND STANDARDS FOR MULTI-CANCER  
25 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;

1           “(F) a comparison of the volume of cov-  
2           ered part D drugs dispensed by essential retail  
3           pharmacies that are network pharmacies for  
4           prescription drug plans offered by PDP spon-  
5           sors and MA–PD plans offered by MA organi-  
6           zations under this part and such volume of dis-  
7           pensing by network pharmacies for such plans  
8           located in similar geographic areas that are not  
9           essential retail pharmacies, including informa-  
10          tion on any patterns or trends in such compari-  
11          son specific to certain types of covered part D  
12          drugs, such as generic drugs or drugs specified  
13          as specialty drugs by a PDP sponsor under a  
14          prescription drug plan or an MA organization  
15          under an MA–PD plan; and

16           “(G) a comparison of the information de-  
17          scribed in subparagraphs (A) through (F) be-  
18          tween essential retail pharmacies that are net-  
19          work pharmacies for prescription drug plans of-  
20          fered by PDP sponsors under this part and es-  
21          sential retail pharmacies that are network phar-  
22          macies for MA–PD plans offered by MA organi-  
23          zations under this part.

24           “(2) DEFINITION OF ESSENTIAL RETAIL PHAR-  
25          MACY.—In this subsection, the term ‘essential retail

1 pharmacy’ means, with respect to a plan year, a re-  
2 tail pharmacy that—

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

5 “(B) is located in—

6 “(i) a medically underserved area (as  
7 designated pursuant to section  
8 330(b)(3)(A) of the Public Health Service  
9 Act);

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

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

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

19 “(3) LIST OF ESSENTIAL RETAIL PHAR-  
20 MACIES.—

21 “(A) PUBLICATION OF LIST OF ESSENTIAL  
22 RETAIL PHARMACIES.—For each plan year (be-  
23 ginning with plan year 2028), the Secretary  
24 shall publish, on a publicly available internet  
25 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-

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

“(iv) EVALUATION OF REMUNERATION ARRANGEMENTS.—Components of subsets of remuneration arrangements (such as fees or other forms of compensation paid to or retained by the pharmacy benefit manager or affiliate of such pharmacy benefit manager), as determined appropriate by the Secretary, between pharmacy benefit managers or affiliates of such pharmacy benefit managers, as applicable, and other entities involved in the dispensing or utilization of covered part D drugs (including PDP sponsors, manufacturers, pharmacies, and other entities as determined appropriate by the Secretary) shall be subject to review by the Secretary, in consultation with the Office of the Inspector General of the Department of Health and Human Services, as determined appro-

1           prios by the Secretary. The Secretary, in  
2           consultation with the Office of the Inspec-  
3           tor General, shall review whether remun-  
4           eration 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 remun-  
11          eration 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—

1           “(A) prohibiting flat dispensing fees or re-  
2           imbursement or payment for ingredient costs  
3           (including customary, industry-standard dis-  
4           counts directly related to drug acquisition that  
5           are retained by pharmacies or wholesalers) to  
6           entities that acquire or dispense prescription  
7           drugs; or

8           “(B) modifying regulatory requirements or  
9           sub-regulatory program instruction or guidance  
10          related to pharmacy payment, reimbursement,  
11          or dispensing fees.

12          “(5) STANDARD FORMATS.—

13               “(A) IN GENERAL.—Not later than June  
14               1, 2027, the Secretary shall specify standard,  
15               machine-readable formats for pharmacy benefit  
16               managers to submit annual reports required  
17               under paragraph (1)(C)(i).

18               “(B) IMPLEMENTATION.—Notwithstanding  
19               any other provision of law, the Secretary may  
20               implement this paragraph by program instruc-  
21               tion or otherwise.

22          “(6) CONFIDENTIALITY.—

23               “(A) IN GENERAL.—Information disclosed  
24               by a pharmacy benefit manager, an affiliate of  
25               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

1           Centers for Medicare & Medicaid Services Pro-  
2           gram Management Account, out of any money  
3           in the Treasury not otherwise appropriated,  
4           \$113,000,000 for fiscal year 2025, to remain  
5           available until expended, to carry out this sub-  
6           section.

7           (B) OIG.—In addition to amounts other-  
8           wise available, there is appropriated to the In-  
9           specter General of the Department of Health  
10          and Human Services, out of any money in the  
11          Treasury not otherwise appropriated,  
12          \$20,000,000 for fiscal year 2025, to remain  
13          available until expended, to carry out this sub-  
14          section.

15          (b) GAO STUDY AND REPORT ON PRICE-RELATED  
16          COMPENSATION ACROSS THE SUPPLY CHAIN.—

17               (1) STUDY.—The Comptroller General of the  
18          United States (in this subsection referred to as the  
19          “Comptroller General”) shall conduct a study de-  
20          scribing the use of compensation and payment struc-  
21          tures related to a prescription drug’s price within  
22          the retail prescription drug supply chain in part D  
23          of title XVIII of the Social Security Act (42 U.S.C.  
24          1395w–101 et seq.). Such study shall summarize in-  
25          formation from Federal agencies and industry ex-



1        perts, to the extent available, with respect to the fol-  
2        lowing:

(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—

11 (i) pharmacy benefit managers;

(ii) PDP sponsors offering prescription drug plans and Medicare Advantage organizations offering MA–PD plans;

15 (iii) drug wholesalers;

16 (iv) pharmacies;

17 (v) manufacturers;

18 (vi) pharmacy services administrative  
19 organizations;

20 (vii) brokers, auditors, consultants,  
21 and other entities that—

22 (I) advise PDP sponsors offering  
23 prescription drug plans and Medicare  
24 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.

1                   “(C) OFF-CAMPUS OUTPATIENT DEPART-  
2                   MENT OF A PROVIDER DEFINED.—For purposes  
3                   of this paragraph, the term ‘off-campus out-  
4                   patient department of a provider’ means a de-  
5                   partment of a provider (as defined in section  
6                   413.65 of title 42, Code of Federal Regulations,  
7                   or any successor regulation) that is not lo-  
8                   cated—

9                   “(i) on the campus (as defined in such  
10                  section) of such provider; or

11                  “(ii) within the distance (described in  
12                  such definition of campus) from a remote  
13                  location of a hospital facility (as defined in  
14                  such section).”.

15           (b) HHS OIG ANALYSIS.—Not later than January  
16 1, 2030, the Inspector General of the Department of  
17 Health and Human Services shall submit to Congress—

18           (1) an analysis of the process established by the  
19           Secretary of Health and Human Services to conduct  
20           the reviews and determinations described in section  
21           1833(t)(23)(B) of the Social Security Act, as added  
22           by subsection (a) of this section; and

23           (2) recommendations based on such analysis, as  
24           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 “\$1,241,000,000”.

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”.

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

3                   **Subtitle A—Extensions**

4   **SEC. 401. EXTENSION FOR COMMUNITY HEALTH CENTERS,**  
5                   **NATIONAL HEALTH SERVICE CORPS, AND**  
6                   **TEACHING HEALTH CENTERS THAT OPERATE**  
7                   **GME PROGRAMS.**

8       (a) EXTENSION FOR COMMUNITY HEALTH CEN-  
9   TERS.—Section 10503(b)(1) of the Patient Protection and  
10   Affordable Care Act (42 U.S.C. 254b–2(b)(1)) is amend-  
11   ed—

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

14               (2) in subparagraph (I), by striking the period  
15   and inserting “, and \$2,315,342,466 for the period  
16   beginning on April 1, 2025, and ending on Sep-  
17   tember 30, 2025; and”;

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

19                       “(J) \$4,600,000,000 for fiscal year 2026;  
20                       and”.

21       (b) EXTENSION FOR THE NATIONAL HEALTH SERV-  
22   ICE CORPS.—Section 10503(b)(2) of the Patient Protec-  
23   tion and Affordable Care Act (42 U.S.C. 254b–2(b)(2))  
24   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”;

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 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       serting “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-  
18minate 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-

1 including, if necessary, provisional data for cal-  
2 endar year 2022.

3 “(B) The highest average rates of unem-  
4 ployment for calendar years 2018 through 2022  
5 based on data provided by the Bureau of Labor  
6 Statistics.

7 “(C) The lowest average labor force par-  
8 ticipation rates for calendar years 2018 through  
9 2022 based on data provided by the Bureau of  
10 Labor Statistics.”;

11 (4) in subsection (g)—

12 (A) in each of paragraphs (1) and (3), by  
13 redesignating subparagraphs (A) and (B) as  
14 clauses (i) and (ii), respectively, and adjusting  
15 the margins accordingly;

16 (B) by redesignating paragraphs (1)  
17 through (3) as subparagraphs (A) through (C),  
18 respectively, and adjusting the margins accord-  
19 ingly;

20 (C) in the matter preceding subparagraph  
21 (A) (as so redesignated), by striking “An enti-  
22 ty” and inserting the following:

23 “(1) IN GENERAL.—An entity”; and

24 (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)—

1 (A) in paragraph (1), by inserting “for  
2 grants awarded prior to the date of enactment  
3 of the SUPPORT for Patients and Commu-  
4 nities Reauthorization Act of 2025” after  
5 “grant period under this section”; and

6 (B) in paragraph (2)—

7 (i) in the matter preceding subpara-  
8 graph (A), by striking “2 years after sub-  
9 mitting the preliminary report required  
10 under paragraph (1)” and inserting “Sep-  
11 tember 30, 2029”; and

12 (ii) in subparagraph (A), by striking  
13 “(g)(3)” and inserting “(g)(1)(C)”; and

14 (7) in subsection (k), by striking “\$5,000,000  
15 for each of fiscal years 2019 through 2023” and in-  
16 serting “\$12,000,000 for each of fiscal years 2025  
17 through 2029”.

18 (b) REAUTHORIZATION OF THE CAREER ACT; RE-  
19 COVERY HOUSING PILOT PROGRAM.—

20 (1) IN GENERAL.—Section 8071 of the SUP-  
21 PORT for Patients and Communities Act (42  
22 U.S.C. 5301 note; Public Law 115–271) is amend-  
23 ed—

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)”; and

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”.

1 (b) EFFECTIVE DATE.—The amendment made by  
2 subsection (a) shall take effect as if enacted on December  
3 29, 2022.

4 **SEC. 554. EXTENSION OF TEMPORARY ORDER FOR**  
5 **FENTANYL-RELATED SUBSTANCES.**

6 Effective as if included in the enactment of the Tem-  
7 porary Reauthorization and Study of the Emergency  
8 Scheduling of Fentanyl Analogues Act (Public Law 116–  
9 114), section 2 of such Act is amended by striking “March  
10 31, 2025” and inserting “September 30, 2026”.

11 **TITLE VI—PANDEMIC AND ALL-**  
12 **HAZARDS PREPAREDNESS**  
13 **AND RESPONSE**

14 **SEC. 601. SHORT TITLE.**

15 This title may be cited as the “Pandemic and All-  
16 Hazards Preparedness and Response Act”.

17 **Subtitle A—State and Local**  
18 **Readiness and Response**

19 **SEC. 611. TEMPORARY REASSIGNMENT OF STATE AND**  
20 **LOCAL PERSONNEL DURING A PUBLIC**  
21 **HEALTH EMERGENCY.**

22 Section 319(e) of the Public Health Service Act (42  
23 U.S.C. 247d(e)) is amended—

24 (1) in paragraph (1), by striking “tribal organi-  
25 zation 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:

1 “(iv) that include, as appropriate, par-  
2 ticipation by relevant industry, academia,  
3 professional societies, and other stake-  
4 holders.”;

5 (iii) in subparagraph (H)—

6 (I) by inserting “and the Direc-  
7 tor of the Office of Pandemic Pre-  
8 paredness and Response Policy” after  
9 “Security Affairs”; and

10 (II) by inserting “and medical  
11 product and supply capacity planning  
12 pursuant to subparagraph (J), includ-  
13 ing discussion of any relevant identi-  
14 fied supply chain vulnerabilities” be-  
15 fore the period at the end;

16 (iv) in subparagraph (I), by inserting  
17 “the Director of the Office of Pandemic  
18 Preparedness and Response Policy,” after  
19 “Security Affairs,”; and

20 (v) in subparagraph (J)(i), in the  
21 matter preceding subclause (I), by insert-  
22 ing “(including ancillary medical supplies  
23 and components of medical products, such  
24 as active pharmaceutical ingredients, key  
25 starting materials, medical device compo-

1 nents, testing kits, reagents, and other  
2 testing supplies)” after “supply needs”;  
3 and

4 (C) in paragraph (7)—

5 (i) in the matter preceding subpara-  
6 graph (A), by inserting “and the require-  
7 ments developed pursuant to paragraph  
8 (3)(B)” after “subsection (d)”;

9 (ii) by redesignating subparagraphs  
10 (E) and (F) as subparagraphs (F) and  
11 (G), respectively; and

12 (iii) by inserting after subparagraph  
13 (D) the following:

14 “(E) include a professional judgment of  
15 anticipated budget needs for each future fiscal  
16 year accounted for in such plan to account for  
17 the full range of anticipated medical counter-  
18 measure needs and life-cycle costs to address  
19 such priorities and requirements;”;

20 (2) in subsection (d)—

21 (A) by amending paragraph (1) to read as  
22 follows:

23 “(1) IN GENERAL.—Not later than March 15,  
24 2020, and biennially thereafter, the Assistant Sec-  
25 retary 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-

1 ing such agents that are an emerging infectious  
2 disease” after “become a pandemic”; and

3 (B) in paragraph (2)(A), by striking  
4 “\$250,000,000 for each of fiscal years 2019  
5 through 2023” and inserting “\$335,000,000  
6 for each of fiscal years 2025 and 2026, to re-  
7 main available through December 31, 2026”.

8 **SEC. 622. NATIONAL HEALTH SECURITY STRATEGY.**

9 Section 2802 of the Public Health Service Act (42  
10 U.S.C. 300hh–1) is amended—

11 (1) in subsection (a)(3)—

12 (A) by striking “In 2022, the” and insert-  
13 ing “The”; and

14 (B) by inserting “, maintaining, and sus-  
15 taining” after “establishing”; and

16 (2) in subsection (b)—

17 (A) in paragraph (2)—

18 (i) in subparagraph (A), by inserting  
19 “that support interagency coordination and  
20 availability of information, as appropriate”  
21 before the period;

22 (ii) in subparagraph (B), by inserting  
23 “rapid testing,” after “and supplies,”;

24 (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: “Not later”.

12   **SEC. 625. STRATEGIC NATIONAL STOCKPILE AND MATE-**  
13                           **RIAL THREATS.**

14          Section 319F–2 of the Public Health Service Act (42  
15          U.S.C. 247d–6b) is amended—

16               (1) in subsection (a)—

17                       (A) in paragraph (2)—

18                               (i) in subparagraph (A), by inserting  
19                               “Such review shall include a description of  
20                               how the Secretary manages and mitigates  
21                               risks associated with gaps between current  
22                               inventory levels and stockpiling goals,  
23                               prioritizes such risks, and tracks progress  
24                               toward mitigation of such risks.” after the  
25                               first sentence; and



1 (ii) in subparagraph (B)(i), by amend-  
2 ing subclause (IV) to read as follows:

3 “(IV) the emergency health secu-  
4 rity threat or threats such counter-  
5 measure procurement is intended to  
6 address, including—

7 “(aa) whether such procure-  
8 ment is consistent with meeting  
9 emergency health security needs  
10 associated with such threat or  
11 threats; and

12 “(bb) in the case of a coun-  
13 termeasure that addresses a bio-  
14 logical agent, whether such agent  
15 has an increased likelihood to be-  
16 come resistant to, more resistant  
17 to, or evade, such counter-  
18 measure relative to other avail-  
19 able medical countermeasures;”;

20 (B) in paragraph (3)—

21 (i) in subparagraph (B), by striking  
22 “are followed, regularly reviewed, and up-  
23 dated with respect to such stockpile” and  
24 inserting “with respect to such stockpile

1 are followed, regularly reviewed, and up-  
2 dated to reflect best practices”;

3 (ii) in subparagraph (I), by inserting  
4 “, through a standard operating proce-  
5 dure,” after “ensure”;

6 (iii) by redesignating subparagraphs  
7 (H) through (K) as subparagraphs (I)  
8 through (L), respectively;

9 (iv) by inserting after subparagraph  
10 (G) the following:

11 “(H) utilize tools to enable the timely and  
12 accurate tracking of the contents of the stock-  
13 pile throughout the deployment of such con-  
14 tents, including tracking of the location and ge-  
15 ographic distribution and utilization of such  
16 contents;”;

17 (v) in subparagraph (K), as so redes-  
18 ignated, by striking “; and” at the end and  
19 inserting a semicolon;

20 (vi) in subparagraph (L), as so redes-  
21 ignated, by striking the period and insert-  
22 ing “; and”; and

23 (vii) by adding at the end the fol-  
24 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

1       determined to be a country of concern as defined in  
2       paragraph (2).

3           “(2) COUNTRIES OF CONCERN.—

4               “(A) DEFINITION.—For purposes of this  
5       subsection, a ‘country of concern’ means the  
6       People’s Republic of China, the Democratic  
7       People’s Republic of Korea, the Russian Fed-  
8       eration, the Islamic Republic of Iran, and any  
9       other country as determined pursuant to sub-  
10      paragraph (B).

11           “(B) ADDITIONAL COUNTRIES.—The Di-  
12      rector of National Intelligence (referred to in  
13      this subsection as the ‘Director’) shall, in con-  
14      sultation with the Secretary, add additional  
15      countries of concern for purposes of paragraph  
16      (1), only if—

17               “(i) the Director determines that evi-  
18      dence exists that a country has malicious  
19      intent related to the creation, enhance-  
20      ment, transfer, or use of pathogens of pan-  
21      demic potential or biological agents or tox-  
22      ins listed pursuant to such section  
23      351A(a)(1); and

24               “(ii) in a manner that does not com-  
25      promise 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

1 individual may be eligible for compensation  
2 under this section with respect to a vaccine  
3 that, at the time it was administered, was in-  
4 cluded in the Vaccine Injury Table under sec-  
5 tion 2114.”; and

6 (ii) in subsection (d)(3)—

7 (I) by striking “This section”

8 and inserting the following:

9 “(A) IN GENERAL.—This section”; and

10 (II) by adding at the end the fol-

11 lowing:

12 “(B) EXHAUSTION OF REMEDIES.—A cov-  
13 ered individual shall not be considered to have  
14 exhausted remedies as described in paragraph  
15 (1), nor be eligible to seek remedy under section  
16 319F–3(d), unless such individual has provided  
17 to the Secretary all supporting documentation  
18 necessary to facilitate the determinations re-  
19 quired under subsection (b)(4).”.

20 (B) TITLE XXI.—Title XXI of the Public  
21 Health Service Act (42 U.S.C. 300aa–1 et seq.)  
22 is amended—

23 (i) in section 2111(a)(2)(A) (42  
24 U.S.C. 300aa–11(a)(2)(A)), in the matter  
25 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-

1           priate, shall appoint to the Advisory Committee  
2           under paragraph (1) at least 13 individuals, in-  
3           cluding the following:

4                   “(i) At least 3 non-Federal health  
5           care providers with expertise in geriatric  
6           medical disaster planning, preparedness,  
7           response, or recovery.

8                   “(ii) At least 3 representatives of  
9           State, local, territorial, or Tribal agencies  
10          with expertise in geriatric disaster plan-  
11          ning, preparedness, response, or recovery.

12                   “(iii) At least 2 non-Federal profes-  
13          sionals with training in gerontology, such  
14          as social workers, scientists, human serv-  
15          ices specialists, or other non-medical pro-  
16          fessionals, with experience in disaster plan-  
17          ning, preparedness, response, or recovery  
18          among other adults.”; and

19          (2) by amending subsection (g) to read as fol-  
20          lows:

21          “(g) SUNSET.—The Advisory Committee shall termi-  
22          nate on December 31, 2026.”.

23          (c) NATIONAL ADVISORY COMMITTEE ON INDIVID-  
24          UALS 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-



1           paredness, response, or recovery for indi-  
2           viduals with disabilities.

3           “(iii) At least 4 individuals with a dis-  
4           ability with expertise in disaster planning,  
5           preparedness, response, or recovery for in-  
6           dividuals with disabilities.

7           “(iv) Other members as the Secretary  
8           determines appropriate, of whom—

9           “(I) at least one such member  
10          shall represent a local, State, or na-  
11          tional organization with expertise in  
12          individuals with disabilities;

13          “(II) at least one such member  
14          shall be an individual with a dis-  
15          ability; and

16          “(III) at least one such member  
17          shall be an individual with expertise in  
18          the needs of housing services, includ-  
19          ing during the response to, and recov-  
20          ery from, disasters.”; and

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

22          “(3) CONSIDERATION.—In appointing members,  
23          including the Chair, to the Committee under this  
24          subsection, the Secretary may give consideration to  
25          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).

1                   **Subtitle D—Additional**  
2                   **Reauthorizations**

3   **SEC. 641. MEDICAL COUNTERMEASURE PRIORITY REVIEW**  
4                   **VOUCHER.**

5           Section 565A(g) of the Federal Food, Drug, and Cos-  
6   metic Act (21 U.S.C. 360bbb–4a) is amended by striking  
7   “October 1, 2023” and inserting “December 31, 2026”.

8   **SEC. 642. EPIDEMIC INTELLIGENCE SERVICE.**

9           Section 317F(c)(2) of the Public Health Service Act  
10   (42 U.S.C. 247b–7(c)(2)) is amended by striking “2019  
11   through 2023” and inserting “2025 and 2026, to remain  
12   available through December 31, 2026”.

13   **SEC. 643. MONITORING AND DISTRIBUTION OF CERTAIN**  
14                   **MEDICAL COUNTERMEASURES.**

15           Section 319A(e) of the Public Health Service Act (42  
16   U.S.C. 247d–1(e)) is amended by striking “2019 through  
17   2023” and inserting “2025 and 2026, to remain available  
18   through December 31, 2026”.

19   **SEC. 644. REGIONAL HEALTH CARE EMERGENCY PRE-**  
20                   **PAREDNESS AND RESPONSE SYSTEMS.**

21           Section 319C–3 of the Public Health Service Act (42  
22   U.S.C. 247d–3c) is amended—

23                   (1) in subsection (b)(3), by striking “under  
24           the” and all that follows through “such Act)” and  
25           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.

1           (2) ASSESSMENT TOPICS.—The topics listed in  
2       this subsection are each of the following:

3           (A) The financial costs of premature birth  
4       to society, including—

5           (i) an analysis of stays in neonatal in-  
6       tensive care units and the cost of such  
7       stays;

8           (ii) long-term costs of stays in such  
9       units to society and the family involved  
10      post-discharge; and

11          (iii) health care costs for families  
12      post-discharge from such units (such as  
13      medications, therapeutic services, co-pay-  
14      ments for visits, and specialty equipment).

15          (B) The factors that impact preterm birth  
16      rates.

17          (C) Opportunities for earlier detection of  
18      premature birth risk factors, including—

19           (i) opportunities to improve maternal  
20      and infant health; and

21           (ii) opportunities for public health  
22      programs to provide support and resources  
23      for parents in-hospital, in non-hospital set-  
24      tings, 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 in-  
juries,” after “related disability,”;

(ii) in paragraph (1), by inserting “,  
including the occupation of the individual,  
when relevant to the circumstances sur-  
rounding 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 sub-  
section (b);

(E) in subsection (b), as so redesignated,  
by inserting “and evidence-based practices to  
identify and address concussion” before the pe-  
riod 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

1 subsection (a). A waiver provided by the Secretary  
2 under this paragraph shall apply only to the fiscal  
3 year involved.”;

4 (C) in subsection (e)(3)(B)—

5 (i) by striking “(such as third party  
6 payers, State agencies, community-based  
7 providers, schools, and educators)”;

8 (ii) by inserting “(such as third party  
9 payers, State agencies, community-based  
10 providers, schools, and educators)” after  
11 “professionals”;

12 (D) in subsection (h), by striking para-  
13 graphs (1) and (2) and inserting the following:

14 “(1) AMERICAN INDIAN CONSORTIUM; STATE.—

15 The terms ‘American Indian consortium’ and ‘State’  
16 have the meanings given such terms in section 1253.

17 “(2) TRAUMATIC BRAIN INJURY.—

18 “(A) IN GENERAL.—Subject to subpara-  
19 graph (B), the term ‘traumatic brain injury’—

20 “(i) means an acquired injury to the  
21 brain;

22 “(ii) may include—

23 “(I) brain injuries caused by an-  
24 oxia 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 PPLICATION 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)”;

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-

1           duct a study of the effectiveness of requiring  
2           assessments and investigations described in sec-  
3           tion 505B of the Federal Food, Drug, and Cos-  
4           metic Act (21 U.S.C.355c), as amended by sub-  
5           section (a), in the development of drugs and bi-  
6           ological products for pediatric cancer indica-  
7           tions, including consideration of any benefits to,  
8           or burdens on, pediatric cancer drug develop-  
9           ment.

10           (B) FINDINGS.—Not later than 10 years  
11           after the date of enactment of this Act, the  
12           Comptroller General shall submit to the Com-  
13           mittee on Energy and Commerce of the House  
14           of Representatives and the Committee on  
15           Health, Education, Labor, and Pensions of the  
16           Senate a report containing the findings of the  
17           study conducted under subparagraph (A).

18   **SEC. 802. ENSURING COMPLETION OF PEDIATRIC STUDY**

19                   **REQUIREMENTS.**

20           (a) EQUAL ACCOUNTABILITY FOR PEDIATRIC STUDY  
21   REQUIREMENTS.—Section 505B(d) of the Federal Food,  
22   Drug, and Cosmetic Act (21 U.S.C. 355c(d)) is amend-  
23   ed—

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 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

“(XII) to the extent feasible, information on the total amount of remuneration for such drug, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer), to the participants and beneficiaries enrolled in such plan or coverage;

“(ii) a list of each therapeutic class (as defined by the Secretary) for which a claim was filed under the group health plan or health insurance coverage during the reporting period, and, with respect to 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 reevaluated  
24       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 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

“(XII) to the extent feasible, information on the total amount of remuneration for such drug, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer), to the participants and beneficiaries enrolled in such plan or coverage;

“(ii) a list of each therapeutic class (as defined by the Secretary) for which a claim was filed under the group health plan or health insurance coverage during the reporting period, and, with respect to 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-

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 (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 reevaluated  
24        by the Secretary every 5 years.

“(8) SPECIFIED LARGE EMPLOYER.—The term ‘specified large employer’ means, in connection with a group health plan (including group health insurance coverage offered in connection with such a plan) established or maintained by a single employer, with respect to a calendar year or a plan year, as applicable, an employer who employed an average of at least 100 employees on business days during the preceding calendar year or plan year and who employs at least 1 employee on the first day of the calendar year or plan year.

“(9) SPECIFIED LARGE PLAN.—The term ‘specified large plan’ means a group health plan (including group health insurance coverage offered in connection with such a plan) established or maintained by a plan sponsor described in clause (ii) or (iii) of section 3(16)(B) that had an average of at least 100 participants on business days during the preceding 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 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-

1                   grams, retail and mail auto-refill pro-  
2                   grams, and cost-sharing assistance incen-  
3                   tives directly or indirectly funded by such  
4                   entity; and

5                   “(vi) total gross spending on all drugs  
6                   under the plan during the reporting 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 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 sec), 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 reevalu-  
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-

ble entity unless 100 percent of rebates, fees,  
alternative discounts, and other remuneration  
received under such contract that are related to  
the utilization of drugs or drug spending under  
such group health plan or health insurance cov-  
erage are remitted to the group health plan or  
health insurance issuer by the entity providing  
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



465

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        metic 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 (a) IN GENERAL.—Section 223(c)(2)(E) of the Inter-  
7 nal Revenue Code of 1986 is amended to read as follows:

8 “(E) SAFE HARBOR FOR ABSENCE OF DE-  
9 DUCTIBLE FOR TELEHEALTH.—

10 “(i) IN GENERAL.—In the case of an  
11 eligible month, a plan shall not fail to be  
12 treated as a high deductible health plan by  
13 reason of failing to have a deductible for  
14 telehealth and other remote care services.

15 “(ii) ELIGIBLE MONTH.—For pur-  
16 poses of this clause, the term ‘eligible  
17 month’ means—

18 “(I) months beginning after  
19 March 31, 2022, and before January  
20 1, 2023,

21 “(II) any month occurring in a  
22 plan year beginning on or before De-  
23 cember 31, 2021, or after December  
24 31, 2022, and before January 1,  
25 2025, and

482

1 “(III) any month occurring in a  
2 plan year beginning after December  
3 31, 2024, and before January 1,  
4 2027, other than months beginning  
5 after December 31, 2024, and before  
6 April 1, 2025.”.

7 (b) EFFECTIVE DATE.—The amendment made by  
8 this section shall apply to plan years beginning after De-  
9 cember 31, 2024.